

## PACKAGING AND SHIPPING SPECIMENS:

**INTRODUCTION:** Employees responsible for shipping laboratory specimens must maintain diagnostic specimens and infectious substances in suitable condition from shipper to consignee. In order to accomplish this, the employee must properly identify, classify, pack, mark, label and document each shipment in accordance with multiple federal and international regulations so as to ensure expeditious transport and timely, accurate test results.

Because diagnostic specimens and infectious substances are considered dangerous goods when transported by air the International Air Transport Association, (IATA) Dangerous Goods Regulations apply. The IATA regulations require that persons responsible for shipping diagnostic specimens and infectious substances by air be trained and certified.

### DEFINITIONS:

**Diagnostic Specimen:** Any human or animal material including, but not limited to, excreta, secretions, blood and its components, tissue and tissue fluids, being transported for diagnostic or investigational purposes, excluding live infective animals. A diagnostic sample is a routine, clinical, non-pathogenic specimen, with no or low risk to both the individual and the community. Specimens of diagnostic nature would include samples being submitted for routine blood lead analysis, genetic screening, blood glucose determinations and the like.

**Infectious Substance:** A substance, clinical specimen or culture, isolate, or other derivative of a clinical specimen that contains or is suspected of containing a viable infectious virus, prion, or a viable microorganism, such as a bacterium, rickettsia, parasite or fungus, that is known or reasonably believed to cause disease in humans. This includes:

- All cultures containing or suspected of containing a microorganism that causes or may cause disease in humans.
- All human or animal clinical specimens that are known or suspected of containing an infectious microorganism or toxin.
- All samples from a patient with serious disease of unknown cause.
- Environmental samples to the extent that they are suspected of containing human pathogens at a level that presents a risk of infection.
- Other specimens designated as infectious by a qualified person such as a physician, scientist or nurse.

Toxins known to be pathogenic are to be packaged and shipped either as infectious substances or as special infectious substances as applicable.

### Risk Groups:

- Risk Group 1: Diagnostic specimen. A micro-organism that is unlikely to cause human or animal disease and is considered **no or low individual or community risk**.
- Risk Group 2: A pathogen that can cause human or animal disease unlikely to be a serious hazard but capable of causing serious infection on exposure. Effective treatment and preventative measures are available; the risk of spread of infection is limited; and there is **moderate individual risk and low community risk**.
- Risk Group 3: A pathogen that causes serious human or animal disease. The disease does not ordinarily spread from one infected individual to another; effective treatment and preventative measures are available; and there is **high individual and low community risk**.
- Risk Group 4: A pathogen that causes serious human or animal disease. The pathogen is readily transmitted from one individual to another directly or indirectly; effective treatment and preventable measures are not usually available; and there is **high individual and community risk**.

**Special Infectious Substance:** Any of the microbiological agents or toxins listed in Section 72.5 (Additional Requirements For Facilities Transferring Or Receiving Select Agents) or Appendix A to 42 CFR, Part 72. These special infectious substances include those agents listed in the CDC/NIH publication "Biosafety in Biomedical Laboratories", as biosafety level (BSL) 4 and most of the BSL 3 agents. Special infectious substances present a high risk of infection and/or death to persons exposed to them either through direct contact, aerosol or ingestion. Shipments of special infectious substances must be tracked to assure their safe arrival.

**Select Agents:** Some organisms listed as special infectious substances are also considered "select agents" and are regulated in USPHS 42 CFR Part 72.6 (Additional Requirements for Facilities Transferring or Receiving Select Infectious Agents). The shipper and receiver of select agents must be registered with the Centers for Disease Control (CDC) and advance arrangements must be made between the shipper and consignee and the shipper and the operator.

These substances must be tracked to ensure safe delivery. A listing of select agents is included as an attachment to this document.

**Hazardous Material:** A substance or material in a quantity and form that may pose an unreasonable risk to health and safety or property when transported in commerce. This term is more commonly used for domestic shipments in the United States (DOT) and is synonymous with the international use of dangerous goods in terms of classification of materials/goods. See definition of dangerous goods.

**Dangerous Goods:** Articles or substances capable of posing a significant risk to health, safety or property when transported by air and which meet the criteria of one or more of nine UN hazard classes and one of three UN packaging groups according to IATA Dangerous Goods Regulations, Section 3.0. The nine classes relate to the type of hazard whereas the packing group relates to the degree of danger within the class, with packing group 1 presenting the greatest danger. Substances in Class 6, Division 6.2 are not assigned packing groups but are categorized by risk group.

- Class 1** - Explosives
- Class 2** - Gases
- Class 3** - Flammable Liquids
- Class 4** - Flammable Solids
- Class 5** - Oxidizing Substances
- Class 6** - **Toxic and Infectious Substances**
  - Division 6.1 - Toxic Substances
  - Division 6.2 - Infectious Substances**
- Class 7** - Radioactive Material
- Class 8** - Corrosives
- Class 9** - **Miscellaneous Goods**
  - Ex: **Carbon dioxide, solid (dry ice)**

**Labeling:** Information concerning the contents of the package and associated hazards; usually printed on paper and affixed to the exterior surface of the package.

**Marking:** Information about the contents and shipment of a package that is printed on or affixed to the exterior surface of a package.

**Overpack:** An enclosure used by a single shipper to contain one or more packages and to form one handling unit for convenience. Dangerous goods packages contained in the overpack must be properly packed, marked, labeled and in proper condition. For cooling purposes, an overpack may contain Carbon dioxide, solid (dry ice), provided that the overpack meets the requirements of IATA Packing Instruction 904.

**Package:** The complete product of the packing operation consisting of the packaging and contents prepared for transport.

**Packaging:** Receptacles and any other components or materials necessary for the receptacle to perform its containment function and to ensure compliance with the minimum packing requirements of the applicable regulations.

- All packagings (new and reused) must be constructed of good quality. The exterior of the outer packaging, where applicable for infectious substances, must clearly state that the packagings meet UN Specifications for Division 6.2 Infectious Substances. All packagings must withstand leakage of contents, punctures, shocks, sudden pressure changes and must resist the effects of temperature, humidity, pressure and vibrations found in normal conditions of transport. Any contaminated packagings must not be reused. Any reusable packagings found to be defective must be discarded.
- Supplies needed. (See individual packaging instructions).

## LOCAL SURFACE TRANSPORT OF A CLINICAL DIAGNOSTIC SPECIMEN

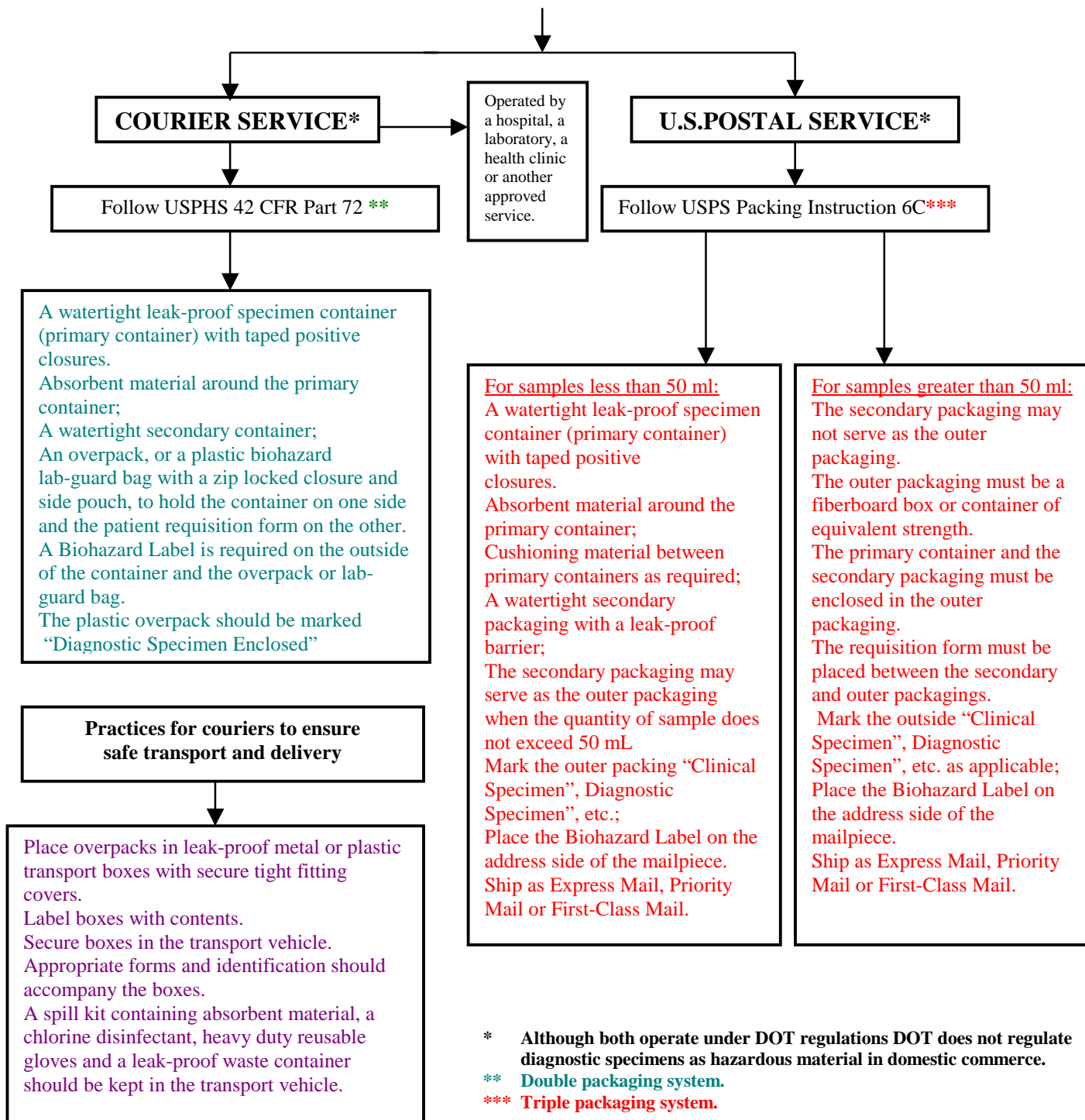
Transport of samples from:

A physician's office to a laboratory;

A hospital to a diagnostic laboratory;

A clinic to a public health laboratory;

A private laboratory or hospital laboratory to a public health laboratory



## LOCAL SURFACE TRANSPORT OF AN INFECTIOUS SUBSTANCE

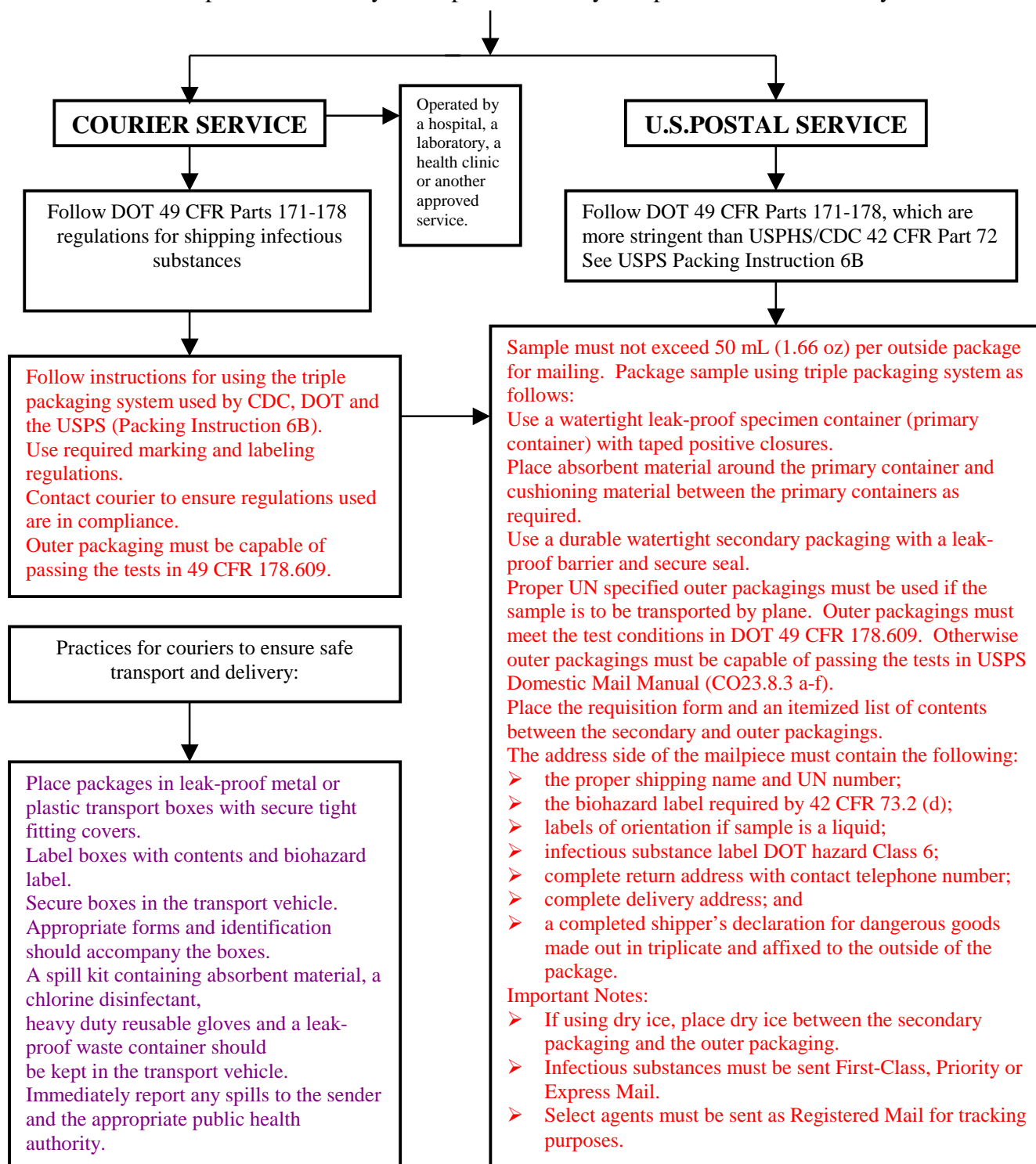
Transport of samples from:

A physician's office to a laboratory;

A hospital to a diagnostic laboratory;

A clinic to a public health laboratory;

A private laboratory or hospital laboratory to a public health laboratory



## SPECIFIC CARRIER INSTRUCTIONS FOR PACKAGING AND SHIPPING DIAGNOSTIC SPECIMENS AND INFECTIOUS SUBSTANCES:

### I. UNITED PARCEL SERVICE-UPS

#### a) DIAGNOSTIC SPECIMEN:

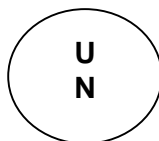
**NOTE: UPS will accept Diagnostic Samples for delivery if they are packaged according to DOT Division 6.2 Hazardous Materials Regulations for Infectious Substances.**

#### MANDATORY PACKAGING REQUIREMENTS:

- A watertight primary container.
- A watertight secondary container.
- An absorbent material to absorb any liquid being shipped.
- A sturdy third package or outer container.
- An overwrap:  
The package must be placed into a **UPS, Next Day Air, Laboratory Pak** marked "**Diagnostic Specimen Enclosed**" on the front of the overwrap.

#### SPECIAL MARKING REQUIREMENTS:

- The words, "Diagnostic Specimen Enclosed" must be marked on the outside of the overwrap.
- The outside of the outer package must bear the markings that clearly identify the package as one that meets **UN Specifications for Division 6.2 Infectious Substances**.
- An example of markings which clearly identify the package as meeting UN specifications for shipment of Infectious Substances:



**Class 6.2/97  
USA/P1234**

**Similar markings must be on the outer packagings used to ship Diagnostic Specimens by UPS.**

#### SPECIAL LABELING REQUIREMENTS:

- The outside of the third container must contain the **International Biohazard Symbol Label** with either a fluorescent orange or fluorescent red background.
- **Labels of orientation** must be used for **liquid** samples.

#### SPECIAL SHIPPING REQUIREMENTS:

- Enclose a completed **UPS Airway Bill**.
- Indicate that **Diagnostic Specimens are enclosed** on the airway bill.
- No other shipping papers are required.

**NOTE (1):** UPS does not ship diagnostic specimens internationally. The UPS Laboratory Pak is to be used only for domestic and Puerto Rico UPS Next Day Air Shipments.

**NOTE (2):** Anything labeled 6.2, Infectious Substance and/or containing dry ice, cannot be shipped inside the UPS Diagnostic Specimen Laboratory Pak.

**NOTE (3):** When using dry ice, use sturdy packaging meeting UN Specifications for the outer packaging. When shipping samples in dry ice for medical or diagnostic purposes, mark the outside of the package and the airway bill, "**Material being refrigerated for medical or diagnostic purposes**". You do not need to use the Class 9 Miscellaneous Label.

## **UNITED PARCEL SERVICE - UPS INFECTIOUS SUBSTANCES:**

**NOTE:** UPS WILL NOT DELIVER OR ACCEPT FOR DELIVERY ANY INFECTIOUS SUBSTANCES. YOU MUST USE ANOTHER CARRIER FOR TRANSPORT.

UPS does not accept nor pick up any packaging which includes the diamond label bearing the words "Infectious Substance"

### **I. UNITED PARCEL SERVICE – UPS b) DRIED BLOOD SPECIMENS:**

Clinical specimens collected by carefully applying a few drops of blood, freshly drawn by finger stick or heel prick with a lancet, onto absorbent specimen collection (filter) paper.

#### **Diagnostic Specimen:**

- Dried blood spot specimens can be shipped or transported with no reasonable expectations of occupational exposure to blood or other potentially infectious material. See **CDC Guidelines for the Shipment of Dried Blood Spot Specimens**, page 3, Risk Evaluation.
- After drying, enclose standard filter paper collection kits (each kit contains a sturdy paper overlay that covers the absorbent filter paper containing the dried specimen), in a high quality paper mailer provided by UPS and seal.
- Fill out UPS Airway Bill and attach to paper mailer, (letter).
- Paper mailers should be extra-strong, tear-proof, air-permeable, and water-resistant envelopes.
- Do not use leak-proof plastic bags because heat buildup and accumulation of moisture within the bag may adversely affect the dried specimen.

#### **Infectious Substance:**

- Do not ship by UPS.
- See packaging requirements of the United States Postal Service.

For more information please see the following references:

**US Postal Service Domestic Mail Manual, Issue 52, dated 07/01/97, Regulation CO23.10.7 Hazardous Matter.**

Guidelines for the Shipment of Dried Blood Spot Specimens, Safety & Health Monograph, Office of Health and Safety, Centers for Disease Control and Prevention (CDC), May 1993.

Procedure for the handling and transport of diagnostic specimens and etiologic agents, Third edition, Approved standard. NCCLS document H5-A3. NCCLS, Wayne, PA, May 1994.

For additional information, call the UPS Hazardous Materials Support Center at 1-800-554-9964. To order Laboratory Paks, call 1-800-PICK-UPS. Visit the UPS Website at: ([www.ups.com](http://www.ups.com))

### **II. FEDERAL EXPRESS – FedEx a) DIAGNOSTIC SPECIMEN:**

**NOTE:** FedEx will accept diagnostic samples for delivery if they are packaged according IATA regulations. See IATA packing instruction number 650, packaging diagnostic samples.

**MANDATORY PACKAGING REQUIREMENTS:**

- A watertight primary receptacle(s). All primary receptacles must have positive closures (such as screw-on, snap-on, or push-on caps) that must be taped.
- A watertight secondary container or packaging.
- An absorbent material placed between the primary receptacle(s) and the secondary container to absorb any liquid being shipped.
- If multiple primary receptacles are placed in the same secondary receptacle, they must be individually wrapped to prevent contact between them.
- Use enough absorbent material must be used to absorb the entire contents of all of the primary receptacles.
- A sturdy third, outer container or package.
- The package size must accommodate all labels, markings and documentation.
- An overwrap - the package must be placed into a **FedEx, Diagnostic Specimen Envelope** marked **"Diagnostic Specimen"** on the front.

**SPECIAL MARKING REQUIREMENTS:**

- Diagnostic Specimen Enclosed, must be clearly marked on the outside.

**SPECIAL LABELING REQUIREMENTS:**

- The outside of the third container must contain the International Biohazard Symbol **Label** with either a fluorescent orange or fluorescent red background. This label must be on containers used for shipping human blood, human blood products, unfixed human tissues, semen, fluids from body cavities and joints, as well as any human body fluids containing visible blood.
- **Labels of orientation** must be used for **liquid** samples.

**SPECIAL SHIPPING REQUIREMENTS:**

- Enclose a completed Federal Express Air Bill.
- Note on the Airway Bill **"Diagnostic Specimens Enclosed."**

**NOTE:** Anything labelled 6.2, Infectious Substance and/or containing Dry Ice, cannot be shipped inside the Diagnostic Specimen Envelope.

## **II. FEDERAL EXPRESS – FedEx**

### **b) INFECTIOUS SUBSTANCE:**

- **Risk Group 2**
- **Risk Group 3**

**NOTE:** FedEx will accept Infectious Substances in Risk Group 2 and in Risk Group 3 for delivery, if they are packaged according to IATA regulations. See IATA packing instruction number 602, packaging infectious substances. FedEx will not accept any Risk Group 4 infectious substances, as these must follow stricter notification policies. You will have to find another carrier to transport infectious substances in Risk Group 4.

**MANDATORY PACKAGING REQUIREMENTS (Risk Group 2 and 3):**

- A watertight primary receptacle(s). All primary receptacles must have positive closures (such as screw-on, snap-on or push-on caps) that must be taped.
- A watertight secondary container or packaging.
- An absorbent material placed between the primary receptacle(s) and the secondary container to absorb any liquid being shipped.
- If multiple primary receptacles are placed in the same secondary receptacle, they must be individually wrapped to prevent contact between them.
- Enough absorbent material must be used to absorb the entire contents of all of the primary receptacles.
- Absorbent material is not required for solid substances.
- A sturdy third, outer container or package consisting of corrugated fiberboard, wood, metal or rigid plastic.

- The package FedEx will accept must be large enough in size to accommodate all markings, labelling and the FedEx documentation. The shipper's declaration may be folded in half and placed into the air waybill pouch with the air waybill.
- All packing materials must meet **UN Specifications** for **Division 6.2 Infectious Substances**.
- An itemized list of contents must be enclosed between the secondary packaging and the outer packaging.

#### **SPECIAL MARKING REQUIREMENTS:**

**Note:** IATA recommends markings be at least 12mm high, except packages of 30L or 30kg capacity or less must be 6 mm minimum height.

- The **Proper Shipping Name** (with the technical name). Example, **Infectious substance, affecting humans**, (Hepatitis B Virus).
- The UN Number, example **UN 2814**
- **Full name and address** of the shipper (**From**) and the Consignee (**To**) marked on the top or side of the package.
- The **name** and **telephone number** of a **person responsible** for the shipment.
- The package must be marked if using dry ice, (**Carbon Dioxide, solid**), **UN 1845**.
- The **net weight** of dry ice in the package must be recorded on the outside of the outer package.
- The outside of the outer package must bear the markings that clearly identify the package as one that meets **UN Specifications** for **Division 6.2 Infectious Substances**.
- Overpacks containing Dry Ice must state "**Inner Packages Comply with Prescribed Specifications**".

#### **SPECIAL LABELING REQUIREMENTS:**

- Arrows or **Package Orientation Labels** are required on combination packages containing liquid. (An exception is infectious substances in primary receptacles of 50 mL or less). When arrows are required, there must be two, one on opposite sides of the package.
- **Hazard label for Infectious Substances, Class 6**.
- **Hazard label for Dry Ice, Miscellaneous, Class 9**, if used.
- **Cargo Aircraft only label**, as it applies. If you are shipping more than 50 mL or 50 g of infectious substance, you need to use the Cargo Aircraft only label, as the shipment will be restricted to cargo. Cross off passenger and cargo on the shipper's declaration. When shipping less than 50 mL or 50 g, you do not need a cargo label and you need to cross off cargo only on the documentation.

#### **SPECIAL SHIPPING REQUIREMENTS:**

- **The shipper must make advance arrangements with the consignee and the operator** (carrier), to ensure that the shipment can be transported and delivered without delay.
- **Complete** and attach a **Federal Express Shippers Declaration**, place it to a pouch, and attach the pouch to the outside of the outer package.
- **Enclose a completed Federal Express Airway Bill**, place it into the pouch containing the shipper's declaration and attach the pouch to the package.

#### **NOTE:**

**Federal Express is a Cargo Airline. Regardless where your package is being shipped, (even if it is only moving 30 miles down the road), it will be shipped under IATA Regulations for Dangerous Goods. Therefore you must package your shipment accordingly as if it were to be shipped by air.**

For more information, call 1-800-GO-FedEx (Ext. 1666) or 800-463-3339 and ask for the Dangerous Goods Hotline or the FedEx Packaging Department at 1-800-633-7019. Website: ([www.fedex.com](http://www.fedex.com))

### **III. UNITED STATES POSTAL SERVICE – USPS**

#### **a) DIAGNOSTIC SPECIMEN: 50 mL or less**



**NOTE: The USPS will accept Diagnostic Samples for delivery if when packaged according to Hazardous, Restricted, and Perishable Mail, Publication 52, Regulation 346.32, (see USPS Packaging Instruction 6C), and the Domestic Mail Manual Regulation CO23.8.0, for Infectious Substances.**

**MAILABILITY:**

- **International Mail:** Only as permitted when written approval has been granted prior to mailing. Prepare for mailing using USPS packing instruction 6B for infectious substances.
- **Domestic Mail:** Permitted only via **Express Mail, Priority Mail, or First-Class Mail** service.

**MANDATORY PACKAGING REQUIREMENTS (USPS Packing Instruction 6C For Diagnostic Specimens Not Exceeding 50 mL Per Mailpiece):**

- A watertight primary receptacle must be durable and securely sealed.
- An absorbent material capable of absorbing any leakage of liquid being shipped must surround the primary receptacle and be sufficient to withstand shock and pressure changes.
- Sufficient cushioning material to withstand shock and pressure changes must surround the primary receptacle.
- A watertight secondary packaging with a leakproof barrier capable of preventing the failure of the secondary packaging should there be leakage from the primary receptacle.
- The secondary packaging may serve as the outer packaging when the quantity of specimen does not exceed 50 mL (1.66 ounces) per mailpiece.

**SPECIAL MARKING REQUIREMENTS:**

The full name and address of the shipper (**From**) and the Consignee (**To**) must be placed on the top or side of the package. The address side must be clearly marked “**Clinical Specimen, Blood Sample**”, “**Clinical Specimen, Urine Sample**”, “**Clinical Specimen, Saliva Sample**”, “**Biological Product**”, etc. where applicable.

**SPECIAL LABELING REQUIREMENTS:**

- The address side of the outer package must contain the **International Biohazard Symbol Label** with either a fluorescent orange or fluorescent red background.
- **Labels of orientation** must be used for **liquid** samples.

**SPECIAL SHIPPING REQUIREMENTS:**

- A Shipper’s Declaration is not required for clinical specimens and biological products that do not contain infectious substances.

### **III. UNITED STATES POSTAL SERVICE – USPS**

#### **b) DIAGNOSTIC SPECIMEN:**

#### **USPS PACKING INSTRUCTION 6C, (CONTINUED)**

**MANDATORY PACKAGING REQUIREMENTS (USPS Packing Instruction 6C For Diagnostic Specimens Exceeding 50 mL Per Mailpiece):**

- A watertight primary receptacle must be durable and securely sealed.
- A single primary receptacle must not contain more than 1,000 mL of a specimen. Multiple primary receptacles are permitted provided a single mailpiece does not contain more than 4,000 mL.
- An absorbent material must surround the primary receptacle or be otherwise configured to absorb all of the liquid content in the primary receptacle in case of leakage.
- Sufficient cushioning material to withstand shock and pressure changes must surround the primary receptacle.
- A watertight secondary packaging with a leakproof barrier capable of preventing the failure of the secondary packaging should there be leakage from the primary receptacle.
- The primary receptacle(s) and the absorbent cushioning must be enclosed in the secondary packaging.
- The secondary packaging can not serve as the outer packaging.

- The outer packaging must be a fiberboard box or a container of equivalent strength.
- The primary receptacle(s), the absorbent cushioning, and the secondary packaging must be enclosed in the outer packaging.
- A single outer packaging must not contain more than 4,000 mL of the specimen material.

#### **SPECIAL MARKING REQUIREMENTS:**

- The full name and address of the shipper (From) and the Consignee (To) on the top or side of the package.
- The address side must be clearly marked “Clinical Specimen, Blood Sample”, “Clinical Specimen, Urine Sample”, “Clinical Specimen, Saliva Sample”, “Biological Product”, etc. where applicable.

#### **SPECIAL LABELING REQUIREMENTS:**

- The address side of the outer package must contain the **International Biohazard Symbol Label** with either a fluorescent orange or fluorescent red background.
- **Labels of orientation** must be used for **liquid** samples.

#### **SPECIAL SHIPPING REQUIREMENTS:**

- A Shipper’s Declaration for dangerous goods is not required for clinical specimens and biological products that do not contain infectious substances.

### **III. UNITED STATES POSTAL SERVICE – USPS**

#### **c) INFECTIOUS SUBSTANCE: Domestic Mail**

**NOTE: The USPS will accept those Infectious Substances permitted to be mailed within specific quantity limits and packaging conditions specified in 346 of the Hazardous, Restricted, and Perishable Mail Regulations, Publication 52, (see USPS Packing Instruction 6B), and the Domestic Mail Manual Regulation CO23.8.0, for Infectious Substances.**

#### **MAILABILITY:**

- **International Mail:** Only as permitted when written approval has been granted prior to mailing.
- **Domestic Mail:** Permitted only via **Express Mail, Priority Mail, or First-Class Mail** service. **Any infectious substance on the CDC listing of select agents, (42 CFR 72.3) must be sent by registered mail service.**

#### **MANDATORY PACKAGING REQUIREMENTS (Separate conditions apply to Domestic and International Mail as noted):**

##### **For Domestic Mail:**

- A watertight primary receptacle (test tube, vial, etc.), must be durable and securely sealed.
- The primary receptacle must be capable of withstanding, without leakage, an internal pressure and temperature as required by 49 CFR 173.196 of the DOT Regulations.
- Multiple primary receptacles are permitted provided the total liquid volume of the infectious substance in all enclosed primary receptacles does not exceed 50 mL per mailpiece.
- Enough cushioning material must surround the primary receptacle and be sufficient to withstand shock, pressure changes, and prevent breakage.
- The space between the primary receptacle(s) and the secondary packaging at the top, bottom, and sides must contain enough material to absorb the entire contents of the primary receptacle(s) in case of leakage or breakage.
- A watertight secondary packaging with a leakproof barrier capable of preventing the failure of the secondary packaging should there be leakage from the primary receptacle and a secure sealing method.
- The secondary receptacle must be capable of withstanding, without leakage, an internal pressure and temperature as required by 49 CFR 173.196 of the DOT Regulations.
- A sturdy third package or outer container, meeting proper UN specifications (a fiberboard box or container of equivalent strength), must be used to enclose the primary receptacle(s) and the secondary packaging.
- No external surface of the outer packaging may be less than 3.9 inches wide (100 mm) as required by 49 CFR 173.196, DOT Regulations.

- Each mailpiece must be designed and constructed so that, if it were subject to the environmental and test conditions in 49 CFR 178.609, DOT Regulations, there would be no significant reduction in the effectiveness of the packaging.

#### **SPECIAL MARKING REQUIREMENTS:**

- **The full name and address** of the shipper (**From**) and the Consignee (**To**) on the top or side of the package.
- The proper shipping name and UN Number, **“Infectious Substances Affecting Animals, UN2900”** or **“Infectious Substances Affecting Humans, UN 2814”** must be clearly marked on the address side

#### **SPECIAL LABELING REQUIREMENTS:**

- The address side of the outer package must contain the Etiologic Agent/ Biohazard Material Label.
- **Labels of orientation** must be used for **liquid** samples to properly indicate upright position of receptacle(s).
- The DOT Hazard Class 6 warning label for **infectious substances**.

#### **SPECIAL SHIPPING REQUIREMENTS:**

- A properly completed **Shipper’s Declaration for Dangerous Goods is required** and must be prepared in **triplicate** and affixed to the outside of the outer packaging.

### **III. UNITED STATES POSTAL SERVICE-USPS**

#### **d) INFECTIOUS SUBSTANCE: International Mail**

#### **MANDATORY PACKAGING REQUIREMENTS:**

##### **For International Mail:**

**Infectious and noninfectious biological substances are permitted in international mail subject to the provisions that apply to domestic mail as noted in the aforementioned regulations. In addition, the following conditions apply:**

- Biological substances are prohibited from international mail by certain countries. To determine if a prohibition exists for a specific country, **check the Individual Country Listings** in the International Mail Manual Regulations, 135-139.
- **Biological substances, including those containing pathogens, must be sent as registered airmail letter packages.**
- Biological substances can be sent to or received by only the following types of institutions when permission has been granted:
  - Laboratories of local, state, and federal government agencies.
  - Laboratories of federally licensed manufacturers of biological products derived from bacteria and viruses.
  - Laboratories affiliated with or operated by hospitals, universities, research facilities, and other teaching institutions.
  - Private laboratories licensed, certified, recognized, or approved by a public authority.
- **Permission to mail biological substances must be obtained prior to mailing.** Qualifying institutions must submit a written letter of application on its organizational letterhead to the following:

##### **MANAGER**

INTERNATIONAL PRICING COSTING AND CLASSIFICATION

INTERNATIONAL BUSINESS UNIT

US POSTAL SERVICE

475 L’ENFANT PLZ SW 370 IBU

WASHINGTON, DC 20260-6500

- The application must state the institution’s nature of work, the identity and qualifications of the prospective recipient, and the number of packages to be mailed.
- **Upon approval**, the requisite number of biological substance **mailing labels will be furnished to the mailer by the Postal Service.**
- **Mailable infectious biological substances are limited to 50 mL per mailpiece** and must be packaged in accordance with **Packaging Instruction 6B**, as well as in accordance with DMM CO23.8.3 and the additional requirements in IMM 135.31 and 135.41.
- A shipper’s declaration for dangerous goods is required for air transportation.

### III. UNITED STATES POSTAL SERVICE-USPS

#### e) Dry Ice

##### (PACKING INSTRUCTION 9A, USPS):

- Articles that include dry ice as a refrigerant for infectious substances must meet the requirements of 42 CFR 72.3 (c) and 49 CFR 173.196(e)(2)(ii).
- The outer package must permit the release of carbon dioxide gas.
- The packaging components should meet UN Specifications.
- The dry ice must be placed outside the secondary receptacle.
- Never place dry ice inside a sealed container.
- Place the dry ice between the secondary container and the outer shipping receptacle.
- Place shock-absorbent material in such a way that the secondary receptacle does not become loose inside the outer packaging as the dry ice dissipates.
- Mark the proper name and UN Number of dry ice on the appropriate side of the outer package, **Carbon dioxide, Solid; UN 1845**.
- Mark the net **weight of dry ice, in kilograms**, on the outside of the outer package.
- For surface transportation each mailpiece must be clearly marked **“Surface Mail Only”**.
- Label using a hazard label for dry ice, **Miscellaneous, Class 9**.

##### Dry Ice Mailability:

- International Mail. Dry ice is prohibited.
- Domestic Mail via Air Transportation, i.e., Express Mail, Priority Mail or First-Class Mail, dry ice is permitted in quantities of up to 5 pounds per mailpiece.
- Domestic Mail via Surface Transportation, i.e., Standard Mail; a mailpiece may contain more than 5 pounds of dry ice.
- Prepare mailpieces using packing instruction 9A

**NOTE:** A mailpiece packaged for surface transportation must not, under any circumstances, be routed via air transportation.

### III. UNITED STATES POSTAL SERVICE – USPS

#### f) DRIED BLOOD SPECIMENS:

Clinical specimens collected by carefully applying a few drops of blood, freshly drawn by finger stick or heel prick with a lancet, onto absorbent specimen collection (filter) paper.

##### Diagnostic Sample:

- Dried blood spot specimens can be shipped or transported with no reasonable expectations of occupational exposure to blood or other potentially infectious material. See **CDC Guidelines for the Shipment of Dried Blood Spot Specimens**, page 3, Risk Evaluation.
- After drying, enclose standard filter paper collection kits (each kit contains a sturdy paper overlay that covers the absorbent filter paper containing the dried specimen), in a high quality bond envelope or paper mailer and seal.
- Paper mailers should be extra-strong, tear-proof, air-permeable, and water-resistant envelopes.
- Mark the outside of the envelope “Dried Clinical Specimens” or “Newborn Screening/Dried Clinical Specimen”.
- Do not use leak-proof plastic bags because heat buildup and accumulation of moisture within the bag may adversely affect the dried specimen and /or the test results.

**Infectious Substance:**

- See packaging requirements of the United States Postal Service.

For more information see the following references:

**US Postal Service Domestic Mail Manual, Issue 52, dated 07/01/97, Regulation CO23.10.7, Hazardous Matter.**

Guidelines for the Shipment of Dried Blood Spot Specimens, Safety & Health Monograph, Office of Health and Safety, Centers for Disease Control and Prevention (CDC), May 1993.

Procedure for the handling and transport of diagnostic specimens and etiologic agents, Third edition, Approved standard. NCCLS document H5-A3. NCCLS, Wayne, PA, May 1994.

**For more information on shipping diagnostic specimens and infectious substances via the United States Postal Service call your local Post Office. Website: ([www.usps.com](http://www.usps.com))**

#### **IV. INTERNATIONAL AIR TRANSPORT ASSOCIATION - IATA**

##### **a) DIAGNOSTIC SPECIMEN: Packing Instruction 650**

Non-pathogenic human or animal material including but not limited to blood and its components, excreta, secretia, tissue and tissue fluids shipped for diagnosis. Materials used for diagnostic screening tests (non-pathogenic, clinical blood specimens) are considered Diagnostic Specimens. Live animals are not included in this category.

##### **Packing Instruction 650**

**Operator Variations: 2.9.3** Variations filed with IATA, more restrictive than IATA regulations and applicable to all transportation performed by the operators concerned.

- **CO-07 Continental Airlines:**

Division 6.2, Infectious Substances, (other than substances transmitted to laboratories for diagnostic purposes or finished biological products bearing the U.S. Government license number of manufacture and intended for human or veterinary use) will not be accepted for carriage.

- **CO-08 Continental Airlines:**

All international and domestic inter-line shipments of dangerous goods, as defined by the Regulations, must be booked with Continental Airlines' Customer Service Center.

- **CS-07 Continental Micronesia:**

Division 6.2 Infectious Substances, (other than substances transmitted to laboratories for diagnostic purposes or finished biological products bearing the U.S. Government license number of manufacture and intended for human or veterinary use) will not be accepted for carriage.

- **FX-09 Federal Express:**

Division 6.2, Risk Group 4 will not be accepted for carriage.

- **QF-05 Quantas:**

Diagnostic Specimens packed in accordance with Packing Instruction 650 are not permitted in the passenger cabin and must be lodged as cargo.

##### **MANDATORY PACKAGING REQUIREMENTS:**

- A watertight primary receptacle(s) – for diagnostic specimens the maximum net quantity must not exceed 500 mL.
- For substances shipped at ambient temperatures or higher, primary receptacles include glass, metal or plastic. Positive means of ensuring leak-proof seal, such as heat seal, skirted stopped or metal crimp seal must be provided. If screw caps are used they must be reinforced with adhesive tape.
- Primary receptacles must be individually wrapped to prevent contact.
- A watertight secondary packaging – the maximum quantity per outer packaging for diagnostic specimens must not exceed 4 L.

- Absorbent material, capable of absorbing the entire contents, must be placed between the primary and the secondary packaging.
- No absorbent material is required when shipping solid substances.
- Enough absorbent material must be used to absorb the entire contents of all of the primary receptacles.
- A sturdy third, outer container or package. Outer packages must be at least 100 mm (4 in.) in the smallest overall external dimension.
- The package size must accommodate all labels, markings and documentation.
- Packaging materials must be of good quality and construction. The outer packagings must pass the drop test.
- An itemized list of all contents must be enclosed between the secondary packaging and the outer packaging.

#### **SPECIAL MARKING REQUIREMENTS:**

- Diagnostic Specimens Packed in Accordance With IATA Packing Instruction 650” must be clearly marked on the outside of each package.
- Full name and address of the shipper (**From**) and the Consignee (**To**) must be marked on the top or side of the package.

#### **SPECIAL LABELING REQUIREMENTS:**

- The outside of the third container must contain the International Biohazard Symbol **Label** with either a fluorescent orange or fluorescent red background. This label must be on containers used for shipping human blood, human blood products, unfixed human tissues, semen, fluids from body cavities and joints, as well as any human body fluids containing visible blood.
- **Labels of orientation** must be used for **liquid** samples.

#### **SPECIAL SHIPPING REQUIREMENTS:**

- Enclose a completed **Air Waybill**.
- The “**Nature and Quantity of Goods**” box of the air waybill must show the text **DIAGNOSTIC SPECIMENS PACKED IN COMPLIANCE WITH IATA PACKING INSTRUCTION 650’**
- A Shipper’s Declaration for Dangerous Goods is **NOT** required.

#### **SPECIFIC SHIPPING REQUIREMENTS:**

**Substances shipped refrigerated or frozen** using wet ice, prefrozen packs, Carbon dioxide, solid (dry ice) or other refrigerant:

- The refrigerant must be placed outside the secondary packaging or in an overpack with one or more completed packagings.
- Interior support must be provided to secure the secondary packaging(s) in the original position after the ice or Carbon dioxide, solid (dry ice) has been dissipated.
- If ice is used the packaging must be leak-proof.
- If Carbon dioxide, solid (dry ice) is used the outer packaging must permit the release of carbon-dioxide gas.
- The primary receptacle must maintain its containment integrity at the temperature of the refrigerant as well as at the temperatures and pressure of air transport to which the receptacle could be subjected if refrigeration were to be lost.

#### **Substances shipped in liquid nitrogen:**

- Plastic capable of withstanding very low temperatures must be used instead of glass receptacles.
- Secondary packaging must also withstand very low temperatures and in most cases will need to be fitted over individual primary receptacles.
- Requirements for shipment of liquid nitrogen must also be observed.
- The primary receptacle must maintain its containment integrity at the temperature of the refrigerant used as well as at the temperatures and pressure of air transport to which the receptacle could be subjected if refrigeration were to be lost.

#### **Lyophilized substances:**

- Primary receptacles must be flame sealed glass ampoules or rubber-stoppered glass vials with metal seals.

## IV. INTERNATIONAL AIR TRANSPORT ASSOCIATION - IATA

### b) INFECTIOUS SUBSTANCE: Packing Instruction 602

Substances known to contain, or reasonably expected to contain pathogens suspected to cause disease in humans or animals. These substances can be human or animal material including but not limited to blood and its components, excreta, secretions, tissue and tissue fluids. Substances shipped for confirmatory testing, known or suspected to contain infectious substances are regulated as Infectious Substances.

#### Packing Instruction 602

**State Variations: 2.9.1** Variations filed with IACO and IATA, more restrictive than IATA regulations and apply to the transport of dangerous goods by air.

➤ **AUG-03 Australia:**

Infectious substances other than human blood products, human urine and human tissue, are prohibited from entry to Australia without prior approval from the Australian Health Authorities.

➤ **CAG-04 Canada:**

Infectious substances are not permitted in the mail in Canada. Infectious substances must documentation and labelling requirements including the requirements outlined in **1.3.3.1** of the IATA Regulations.

➤ **USG-13 United States:**

A copy of the Shipper's Declaration must be retained by the operator for not less than 90 days. In the event of leakage from, a package containing infectious substances within the United States, the Center for Disease Control (CDC) in Atlanta, Georgia, must be notified immediately at the following telephone number: **1-(404) 633-5313**.

➤ **VUG-02 Vanuatu:**

Infectious substances are prohibited from entry to Vanuatu without prior approval from the Vanuatu Government Department of Health. (Director of Health/P.O. Box 102/Port-Vila/Vanuatu)

**Operator Variations: 2.9.3** Variations filed with IATA, more restrictive than IATA regulations and applicable to all transportation performed by the operators concerned.

➤ **5X-04 United Parcel Service:**

The following classes/divisions of dangerous goods are prohibited from UPS international small package and Air Cargo services under any circumstances: Division 6.2, (Infectious Substances).

➤ **AF-04 Air France:**

All blood extracts and biological samples, human or animal origin, must be classified as UN 2814, Infectious substance, affecting humans, liquid form in Division 6.2 and packed according to Packing Instruction 602. The exception would be safe human blood destined for treatment or transfusion for humans or blood plasma. The shipment and air waybill must be classified as non-dangerous pharmaceuticals, life-saving drugs.

➤ **AS-02 Alaska Airlines:**

Division 6.1, no substance required to bear a "Toxic" label will be accepted for discharge.

➤ **AS-08 Alaska Airlines:**

Division 6.2 Infectious substances (other than those substances transmitted to laboratories for diagnostic purposes or finished biological products bearing the U. S. Government license number of manufacture and intended for human or veterinary use) will not be accepted for carriage.

➤ **CI-01 China Airlines:**

consignment of dangerous goods as shown in Subsection 4.2 of the IATA Regulations will not be accepted for carriage by China Airlines on its international passenger flights and domestic flights.

➤ **CO-07 Continental Airlines:**

Division 6.2, Infectious Substances, (other than substances transmitted to laboratories for diagnostic purposes or finished biological products bearing the U.S. Government license number of manufacture and intended for human or veterinary use) will not be accepted for carriage.

➤ **CO-08 Continental Airlines:**

All international and domestic inter-line shipments of dangerous goods, as defined by the Regulations, must be booked with Continental Airlines' Customer Service Center.

- **CS-07 Continental Micronesia:**  
Division 6.2 Infectious Substances, (other than substances transmitted to laboratories for diagnostic purposes or finished biological products bearing the U.S. Government license number of manufacture and intended for human or veterinary use) will not be accepted for carriage.
- **FX-09 Federal Express:**  
Division 6.2, Risk Group 4 will not be accepted for carriage.
- **SW-01 Air Namibia:**  
Dangerous goods, as defined in IATA Regulations, will not be accepted for carriage on the Beechcraft B1900 Aircraft.
- **US-08 US Airways, Inc.:**  
Division 6.2 Infectious Substances will not be accepted when the per package limit exceeds 50 mL per package.

#### **MANDATORY PACKAGING REQUIREMENTS:**

- A watertight primary receptacle(s). All primary receptacles must have positive closures (such as screw-on, snap-on or push-on caps) that must be taped.
- A watertight secondary container or packaging.
- An absorbent material must be placed between the primary receptacle(s) and the secondary packaging to absorb any liquid being shipped.
- If multiple primary receptacles are placed in the same secondary receptacle, they must be individually wrapped (or for infectious substances transported in liquid nitrogen), separated and supported, to prevent contact between them.
- Use enough absorbent material to absorb the entire contents of all of the primary receptacles.
- Absorbent material is not required for solid substances.
- A sturdy third, outer container or package consisting of corrugated fiberboard, wood, metal or rigid plastic. The outer packaging must be of sufficient strength to meet the design type tests in Subsection 6.5 and bear the specification markings.
- All packing materials must meet **UN Specifications for Division 6.2 Infectious Substances**.
- The outer package must be large enough in size to accommodate all markings, labelling and documentation.
- An itemized list of contents must be enclosed between the secondary packaging and the outer packaging.
- Packages must be at least 100 mm (4in) in the smallest overall external dimension.

#### **SPECIAL MARKING REQUIREMENTS:**

Note: IATA recommends markings be at least 12mm high, except packages of 30L or 30kg capacity or less must be 6 mm minimum height.

- The **Proper Shipping Name** (with the technical name). Example, **Infectious substance, affecting humans**, (Hepatitis B Virus).
- The UN Number, example **UN 2814**
- **Full name and address** of the shipper (**From**) and the Consignee (**To**) marked on the top or side of the package.
- The **name and telephone number** of a **person responsible** for the shipment must be marked durably and legibly on the outer packaging.
- The package must be marked if using dry ice, (**Carbon dioxide, solid**), **UN 1845**.
- The **net weight** of dry ice in the package must be recorded on the outside of the outer package.
- The outside of the outer package must bear the markings that clearly identify the package as one that meets **UN Specifications for Division 6.2 Infectious Substances**.
- Overpacks containing Dry Ice must state “**Inner Packages Comply with Prescribed Specifications**”.

#### **SPECIAL LABELING REQUIREMENTS:**

- Arrows or **Package Orientation Labels** are required on combination packages containing liquid. (An exception is infectious substances in primary receptacles of 50 mL or less). When arrows are required, there must be two, one on opposite sides of the package.
- **Hazard label for Infectious Substances, Class 6**.
- **Hazard label for Dry Ice, Miscellaneous, Class 9**, if used.



- **Cargo Aircraft Only label**, as it applies. When shipping more than 50 mL or 50 g of infectious substance, you need to use the Cargo Aircraft only label, as the shipment will be restricted to cargo. Cross off passenger and cargo on the shipper's declaration. If shipping less than 50 mL or 50 g, you do not need a cargo label and you need to cross off cargo only on the documentation.

#### **SPECIAL SHIPPING REQUIREMENTS:**

- **The shipper must make advance arrangements with the consignee and the operator** (carrier), to ensure that the shipment can be transported and delivered without delay.
- The following required statement (8.1.6.11.3) must be included in the Additional Handling Information area of the Shipper's Declaration: **"Prior arrangements as required by the IATA Dangerous Goods Regulations 1.3.3.1 have been made"**.
- **Complete** and attach a **Shippers Declaration**, place it to a pouch, and attach the pouch to the outside of the outer package.

#### **SPECIFIC SHIPPING REQUIREMENTS:**

**Substances shipped refrigerated or frozen** using wet ice, prefrozen packs, Carbon dioxide, solid (dry ice) or other refrigerant:

- The refrigerant must be placed outside the secondary packaging or in an overpack with one or more completed packagings.
- Interior support must be provided to secure the secondary packaging(s) in the original position after the ice or Carbon dioxide, solid (dry ice) has been dissipated.
- If ice is used the packaging must be leak-proof.
- If Carbon dioxide, solid (dry ice) is used the outer packaging must permit the release of Carbon-dioxide gas.
- The primary receptacle must maintain its containment integrity at the temperature of the refrigerant as well as at the temperatures and pressure of air transport to which the receptacle could be subjected if refrigeration were to be lost.

#### **Substances shipped at ambient or higher temperatures:**

- Primary receptacles may only be of glass, metal or plastic. Positive means of ensuring a leak-proof seal must be provided, such as heat seal, skirted stopper or metal crimp seal. If screw caps are used, these must be reinforced with adhesive tape.

**For more information and technical assistance with Dangerous Goods call The Dangerous Goods International at 904-491-0925, or fax at 904-491-0989, Website: ([www.dgitraining.com](http://www.dgitraining.com))**  
**IATA telephone number: 514-390-6757, IATA fax 514-874-2660**

#### **WEB SITES FOR LISTINGS OF INFECTIOUS SUBSTANCES BY RISK GROUP:**

- <http://www.tc.gc.ca/acts/regs>
- <http://www.absa.org/riskgroups/index.html>
- <http://www.hc-sc.gc.ca/hpd/lcdc/biosafety/docs/index.html>

## PROCEDURE FOR THE TRANSFER OF SELECT AGENTS FOR NON-EXEMPTED LABORATORIES

**Summary:** The Department of Health and Human Services has published regulations regarding the access, use and transfer of select agents for research purposes. Select agents are those biological agents that have the potential to pose a severe threat to public health and safety. The list of “Select Agents” includes approximately 40 viruses, bacteria, rickettsia, fungi and toxins whose transfer in the United States is controlled by The Centers for Disease Control and Prevention. See a listing of select agents in the attachment section at the end of this document.

The regulation, Title 42 CFR Part 72 .6, “Additional Requirements for Facilities Transferring or Receiving Select Agents”, was designed to ensure the following:

- that infectious agents and toxins listed as select agents are shipped only to institutions or individuals registered with CDC or CLIA-certified who are equipped to handle select agents;
- that select agents are shipped only to those who have legitimate reasons to use them;
- and that the system implemented, whereby scientists and researchers involved in legitimate research involving transferring and receiving agents, could continue without undue burden.

Prior to the transfer of select agents, both the facility shipping the select agent (shipper/transferor) as well as the facility receiving the select agent (consignee/requestor) must be registered with CDC in Atlanta, Georgia unless they meet the requirements for exemption.

Research and clinical exemptions exist. Specific strains of some infectious agents and certain toxins are exempt for research purposes. Clinical specimens sent to Clinical Laboratories (CLIA certified) may also be exempt under certain conditions.

### How to Register with CDC

To register with CDC, contact CDC, Office of Health and Safety, Laboratory Registration/Select Agent Transfer (LR/SAT) Program by one of the following means:

- a) By fax: 404-639-0880
- b) By e-mail [lrsat@cdc.gov](mailto:lrsat@cdc.gov)
- c) By phone: 404-639-4419

The LR/SAT Program is responsible for both the registration and on-site inspection process to assure that the facility meets the biosafety level requirements for working with the select agent in question.

The facility must request an application package for select agents by fax or e-mail.

The facility must fill out the application request and return it to the CDC, LR/SAT Program.

CDC will contact the facility to review the application, clear up any questions pertaining to the application and arrange for the on-site inspection if necessary.

Each registered facility must have in place procedures for the disposal of select agents on-site.

Each registered facility must designate a responsible facility official (RFO) to oversee the process which includes signing each request certifying that the consignee is affiliated with the requesting facility and that the laboratory meets the biosafety requirements and guidelines for working with the requested agent.

Registered facilities are issued a registration number that must be used as a part of the transfer process from one facility to another. CDC sends a registered certification along with CDC form EA-101. These are sent to the facility by fax and by U. S. Mail.

## **How to use CDC Form EA-101**

Form (CDC) EA-101, the required documentation necessary for the transfer of select agents, must be completed for each transfer of a select agent. A paper copy must be kept by the RFO for a minimum of five years or the RFO must retain the record 5 years after the agent is consumed, exhausted or destroyed, whichever is longer.

### **Shipment of a select agent to the consignee:**

1. The shipper's RFO must verify with the consignee's RFO, and if necessary, with CDC, that the requesting facility:
  - a) maintains a valid and current registration for the select agent being requested;
  - b) that the person requesting the select agent is an employee of the requesting facility and that;
  - c) the proposed use of the agent by the requestor is correctly indicated on form EA-101.

**NOTE:** CDC recognizes that the select agent registration certificate does not contain information regarding which specific select agent(s) a facility is registered for. Contact CDC for verification:

- if the sender cannot verify the registration status of the consignee;
  - if there is any suspicion that the agent may not be used for the requested purpose;
  - if there are any other concerns.
2. After the shipper verifies the above information, he/she fills in blocks 1 and 2 of the EA-101 and properly packages the material for shipment to the consignee.
  3. Select agents must be packaged, marked, labeled and shipped in accordance with all federal (42 CFR 72 and 49 CFR 100-180) and international (IATA) regulations.
  4. The shipper should utilize a mechanism for tracking the select agents shipped.
    - Call ahead to notify the consignee of the shipping date.
    - Have the consignee notify the shipper by phone or e-mail within 36 hours that the package was received intact and on what date the package was received.
    - Record this information for record purposes.
    - A return receipt is required by law for select agents listed in 42 CFR Part 72.3. See the listing of these agents in the attachment section at the end of this document.
  5. The shipper also fills out Section 3 and the shipping information in Section 4, including the date of shipment.

### **Receipt of the select agent by the consignee:**

1. The consignee's RFO must acknowledge receipt of the agent to the shipper electronically or by phone within 36 hours of receipt.
2. The consignee's RFO is required to provide a paper copy or facsimile transmission of receipt to the sender within three business days of the receipt.

### **Submitting form EA-101 to CDC:**

1. After acknowledgement of the receipt by the consignee, the shipper writes in the date the agent was received in block 4 of form EA-101.
2. The shipper must provide a completed paper copy or FAX of form EA-101 within 24 hours to CDC.
3. A completed copy of form EA-101 is sent to the consignee at the same time.

### **Destruction or depletion of a transferred select agent:**

1. The RFO of the facility must complete Section 5 of EA-101.
2. A copy or FAX of EA-101 must be sent to CDC

## **PROCEDURE FOR THE TRANSFER OF SELECT AGENTS BETWEEN CLIA-CERTIFIED AND NON-EXEMPTED LABS**

Since CLIA-certified laboratories using select agents for exempt purposes are not required to register with CDC, CDC cannot verify that a CLIA laboratory is authorized to receive, or is capable of handling a select agent. When a registered facility receives a request from a CLIA-certified laboratory for a select agent, CDC recommends the following:

- the CLIA laboratory must provide the non-CLIA laboratory with a copy of their current CLIA certificate;
- the CLIA laboratory must provide the non-CLIA laboratory with a signed statement that their facility is capable of safely handling the select agent in question;
- the CLIA laboratory must verify in writing that the select agent will only be used for the purposes that are exempt from the regulation.

## **PROCEDURE FOR THE TRANSFER OF SELECT AGENTS FOR EXEMPTED CLIA-CERTIFIED LABORATORIES**

**Summary:** Regulation, 42 CFR 72.6, specifically exempts from the provisions of Section 72.6 clinical laboratories certified under the Clinical Laboratory Improvement Amendments of 1988, (42 U.S.C. 263a) (CLIA) that utilize select agents for the following:

- Diagnostic purposes
- Reference purposes
- Verification purposes
- Proficiency testing purposes

The regulation provides procedures for facilities that are not CLIA laboratories but are transferring or receiving select agents to or from CLIA laboratories. No additional paperwork on behalf of CLIA laboratories is required by the regulation. CDC will accept a CLIA certification number on CDC Form EA-101 in lieu of the required assigned registration number.

Facilities that are not CLIA laboratories but are transferring or receiving select agents to or from a CLIA laboratory must comply with the following provisions:

1. **Prior to shipping a select agent to a CLIA laboratory, the shipper (transferor) must:**
  - a. Provide the following information on CDC Form EA-101:
    - The name of the consignee and the requesting facility;
    - The name of the shipper and the transferring facility;
    - The name of the shipper's responsible facility official ;
    - The consignee facility's CLIA certification number (which the shipper must verify with the registering entity as being valid and current);
    - The shipper's facility's registration number;
    - The name of the select agent(s) being shipped;
    - The proposed use of the select agent(s);
    - The quantity (i.e., the number of containers and the amount per each container) of the select agent(s) being shipped.
  - b. Verify receipt of the select agent with the CLIA laboratory and note the receipt on CDC Form EA-101
  - c. Transmit by FAX a copy of the form, signed by the shipper and the shipper's RFO to the registering entity holding the registration of the shipper's facility, (CDC).
  - d. There are three copies to Form EA-101; one copy stays with the shipper, one copy is sent to the consignee and one copy is sent to CDC.
  - e. Retain a copy of Form EA-101. A paper copy must be kept by the shipper's RFO for a minimum of five years or the RFO must retain the record 5 years after the agent is consumed, exhausted or destroyed, whichever is longer.
2. **Prior to receiving a select agent from a CLIA laboratory, the consignee must** be registered in accordance with Section 72.6 (a) and comply with the following requirements:

- a. Provide the following information on CDC Form EA-101:
  - The name of the consignee and the requesting facility;
  - The name of the shipper and the transferring facility;
  - The name of the consignee's responsible facility official;
  - The CLIA certification number of the shipper's facility;
  - The consignee's registration number for the facility;
  - The name of the select agent(s) being shipped;
  - The proposed use of the select agent(s);
  - The quantity (i.e., the number of containers and the amount per each container) of the select agent(s) being shipped.
- b. Upon receiving the agent, the consignee notes the date of receipt on Form EA-101.
- c. The consignee must FAX a copy of Form EA-101, signed by the consignee and the consignee's RFO, to the registering entity holding the consignee facility's registration, CDC).
- d. The RFO retains a copy of Form EA-101 for a minimum of five years or the RFO must retain the record 5 years after the agent is consumed, exhausted or destroyed, whichever is longer.
- e. Complies with the disposal requirements of Section 72.6(i):
  - The RFO of the facility must complete Section 5 of EA-101.
  - A copy or FAX of Form EA-101 must be sent to CDC.

**DUTIES OF RESPECTIVE RESPONSIBLE FACILITY OFFICIALS (RFO) FOR FILLING  
IN CDC FORM EA-101 FOR THE TRANSFER OF SELECT AGENTS**

<b>CONSIGNEE RFO REQUESTOR RFO RECEIVER RFO</b>	<b>SHIPPER RFO TRANSFEROR RFO SENDER RFO</b>
<b>1.</b> Completes agent description (Block 1 )	
<b>2.</b> Completes requestor information (Block 2)	
<b>3.</b> Faxes Form EA-101 and registration certificate to shipper	
	<b>4.</b> Verifies registration information
	<b>5.</b> Completes shipper information
	<b>6.</b> Completes shipping/packing information
	<b>7.</b> Oversees packaging and shipment of agent to consignee (requestor). Sends shipment.
<b>8.</b> Receives select agent and records date	
<b>9.</b> Notifies shipper's (transferor's) RFO of receipt via FAX or Phone within 36 hours; provides paper copy within 3 days.	
	<b>10.</b> Shipper enters date select agent received by consignee in Block 4 of Form EA-101
	<b>11.</b> Shipper faxes completed Form EA-101 to CDC within 24 hours
<b>12.</b> Retains paper record for 5 years or 5 years after the agent is Used up or destroyed, whichever is longer.	<b>12.</b> Retains paper record for 5 years or 5 years after the agent is used up or destroyed, whichever is longer.
<b>13.</b> Record the date of consumption/destruction on Form EA-101 And FAX a copy to CDC	<b>13.</b> Record the date of consumption/destruction on Form EA-101 and FAX a copy to CDC

## EXPORT OR IMPORT OF INFECTIOUS SUBSTANCES, AFFECTING HUMANS AND/OR INFECTIOUS SUBSTANCES, AFFECTING ANIMALS.

- Is an export license required to ship the organism?

In order to assess whether or not an export/import license is required for shipping the organism, look up the organism on the Commerce Control Listing established by the Department of Commerce in 15 CFR Parts 730 to 799. The listing can be found in Part 774, Section 774.1, Supplement No. 1 of the Export Administration Regulations.

The following excerpts from the Commerce Control Listing should be reviewed:

- ◆ **1C351** Infectious substances, affecting humans; human pathogens, zoonoses and toxins
- ◆ **1C352** Infectious substances, affecting animals; animal pathogens
- ◆ **1C353** DNA or genetically modified micro-organisms
- ◆ **1C354** Plant pathogens
- ◆ **1C991** Vaccines, immunotoxins and medical products

If the organism to be shipped is on any of the above lists, (NOTE: listings 1C351 and 1C352 include infectious substances), then an export license is required for international shipment.

- If an export license is required, contact the Department of Commerce, (DOC), Bureau of Export Administration at 202-482-4811 or through the internet at <http://www.bxa.fedworld.gov> or <http://www.bxa.doc.gov> for information on:
1. obtaining a license, ECCN, (if needed);
  2. filling out the shipper's declaration and any other required paperwork which must accompany the shipper's declaration;
  3. electronic services; and
  4. obtaining forms by phone.
- ◆ For answers to specific questions regarding export / import licenses, contact Douglas Brown at 202-482-5808.
- Where is the organism being shipped? What is the exact country and location of destination? What documentation is required to accompany the organism? Some countries have restrictions and variances regarding export/import of infectious substances. Check with CDC, DOC, the Airline Carrier or Courier. Federal Express (Airline Carrier) will check out restrictions or variances and tell you exactly what documents are required as well as how to fill them out correctly. For assistance in this area call FedEx at 1-800-247-4747.
- Does the consignee need an import license? Are there any conditions regarding importing infectious substances attached to the specific license? Find out the above information by contacting the consignee directly by phone or e-mail. Ask the consignee to send by mail or fax, a copy of their import license complete with any attachments to the license. It is important to review all conditions set forth in the attachments to the license as these may include additional paperwork and documentation required from the shipper, which must accompany the international air waybill and shipper's declaration as a condition of transport. If you have questions contact the following sources for clarification:
1. Contact CDC at 404-639-3354, (ask for Yvonne Stiffel), for information on obtaining export/import licenses, risk group classification and restrictions regarding export/import;
  2. Contact the Department of Commerce, Bureau of Export Administration for information on obtaining the license, ECCN, (if needed); filling out the shipper's declaration and any other required paperwork which must accompany the shipper's declaration; electronic services; and obtaining forms by phone; call 202-482-4811 or 949-660-0144. For answers to specific questions contact Douglas Brown at 202-482-5808.

The fax number for DOC is 202-482-3617. You may also contact DOC through the Internet at <http://www.bxa.fedworld.gov> or <http://www.bxa.doc.gov>

3. Contact the airline carrier of choice to review the conditions set forth in the license and ensure that you have all the proper paperwork required as a condition of transport.

- Note the proper shipping name, technical name and UN number of the organism. Example: if shipping *Bordetella holmesii* the proper shipping name is **Infectious substance, affecting humans**, the technical name, which must appear in brackets under the proper shipping name, is (*Bordetella holmesii*), and the UN number is **2814**. This information must be marked clearly and uniformly on the outside of the outer package and on all required documentation as required by IATA, DOC, USPS, and courier specific regulations.

If shipping an organism that affects both humans and animals, ship the organism as Infectious substance, affecting humans.

- To what risk group does the organism belong? Check the **CDC or Transport Canada listings**, etc. for risk group classifications. If the organism is unclassified or there is doubt about the classification, package and ship the organism as an infectious substance.
- Is the organism on the **CDC List of Select Agents**? Check the CDC listing and follow the instructions for the select agent rule. Find out whether or not a form EA 101 is required. If you have questions pertaining to the select agent rule contact CDC at the following:
  1. By phone: 404-639-4418  
404-639-4419 (Mark Hemphill)
  2. By fax: 404-639-0880
  3. By e-mail: [lrsat@cdc.gov](mailto:lrsat@cdc.gov)
  4. By internet: <http://www.cdc.gov/od/ohs/lrsat/applictn.htm>
- Is the organism on the **Specified Animal Pathogen List** in the Schedule to the Specified Animal Pathogens Order of 1998? Some import licenses may have this stipulation as a condition attached to the license. Check the listing at the end of this document.
- Examples of some documentation required by the airline carrier or as a condition to the import license:

**Note:** Documentation required may vary from country to country or from licensee to licensee within country, due to the conditions attached to the consignees specific import license.

1. **Shipper's Declaration** or a **Shipper's Export Declaration**.
2. A **Commercial Invoice**, the original and one copy are required to accompany the air waybill.
3. An **International Air waybill**.
4. A **letter to the international customs agent** which must be on official letterhead containing a complete description of the isolate, with a statement that the isolate is to be used for research purposes only.
5. The **"To Whom It May Concern" letter** on official letterhead stating that the culture is pure and free from all infectious agents listed in the **Schedule to the Specified Animal Pathogens Order of 1998**.
6. A **letter to the consignee** on official letterhead stating the contents of the package, the fact that the organism is to be used for research purposes only, and whom to contact should problems or questions arise concerning the isolate. Include the phone number and e-mail address of the shipper. This letter goes inside the outer packaging.



7. Documents numbered 1 through 5 should be included inside the document pouch which should be attached to the outside of the outer packaging in such a way as it does not obstruct or overlap any required markings or labels.
  8. The required markings, labels and documentation will dictate the size of the outer packaging.
- What quantity is being shipped? The quantity will determine transport by passenger/cargo or cargo aircraft only. The maximum quantity per package of infectious substance allowed on a passenger and cargo aircraft is 50 mL, or 50 grams. The maximum quantity per package allowed on cargo aircraft only is 4 liters or 4 kilograms. The maximum quantity per package of diagnostic specimen allowed is 4 liters or 4 kilograms, (for both passenger and cargo or cargo aircraft only).
  - If traveling by plane IATA Regulations prevail including identifying, classifying, packaging, marking, labeling and documenting. Use UN specified packagings for infectious substances, Class 6.2.
  - It is **important to phone ahead and let the consignee know when the package is to be shipped** and by what airline, etc. It is equally important that the consignee **immediately notify the shipper upon receipt of the package**. The shipper should record the date of receipt by the consignee on the original consignment paperwork.

**Some attachments which may be requested as a condition of transport:**

- Commerce Control List
- Listing of Infectious Substances by Risk Group Classification, taken from the Canadian Transportation of Dangerous Goods Act
- CDC Listing of Select Agents
- Schedule to the Specified Animal Pathogens Order 1998
- Copy of an import license
- Copy of conditions attached to an import license
- Blank Commercial Invoice (The original and one copy must accompany the International Air waybill)
- Instructions for filling in the Commercial Invoice
- Sample of a completed Commercial Invoice non-specific
- Sample of a completed Commercial Invoice as it relates to infectious substances
- Blank Shipper's Declaration
- Instructions for filling out a Shipper's Declaration
- Completed Shipper's Declaration
- Completed International Air waybill
- Example of letter to International Customs Agent
- Example of a letter stating that the material is free of any infectious agents listed in the Schedule to the Specified Animal Pathogens Order of 1998 addressed to "Whom it may concern".
- Example of letter to consignee listing the contents and stating that the organism is to be used for research purposes only.

## **DOCUMENTATION:**

**Air Waybill:** <http://www.fedex.com/us/government/airbill>

**Dangerous Goods Airbill:** <http://www.fedex.com/us/government/shippingdocs>.

**Shipper's Declaration:** <http://www.fedex.com/us/government/shippingdocs>.

**Commercial Invoice:** <http://www.fedex.com/us/government/international/documents>)

**International Air Waybill:** <http://www.fedex.com/us/government/international/documents>)

**CDC Form EA-101 for Select Agents:** [lrsat@cdc.gov](mailto:lrsat@cdc.gov)

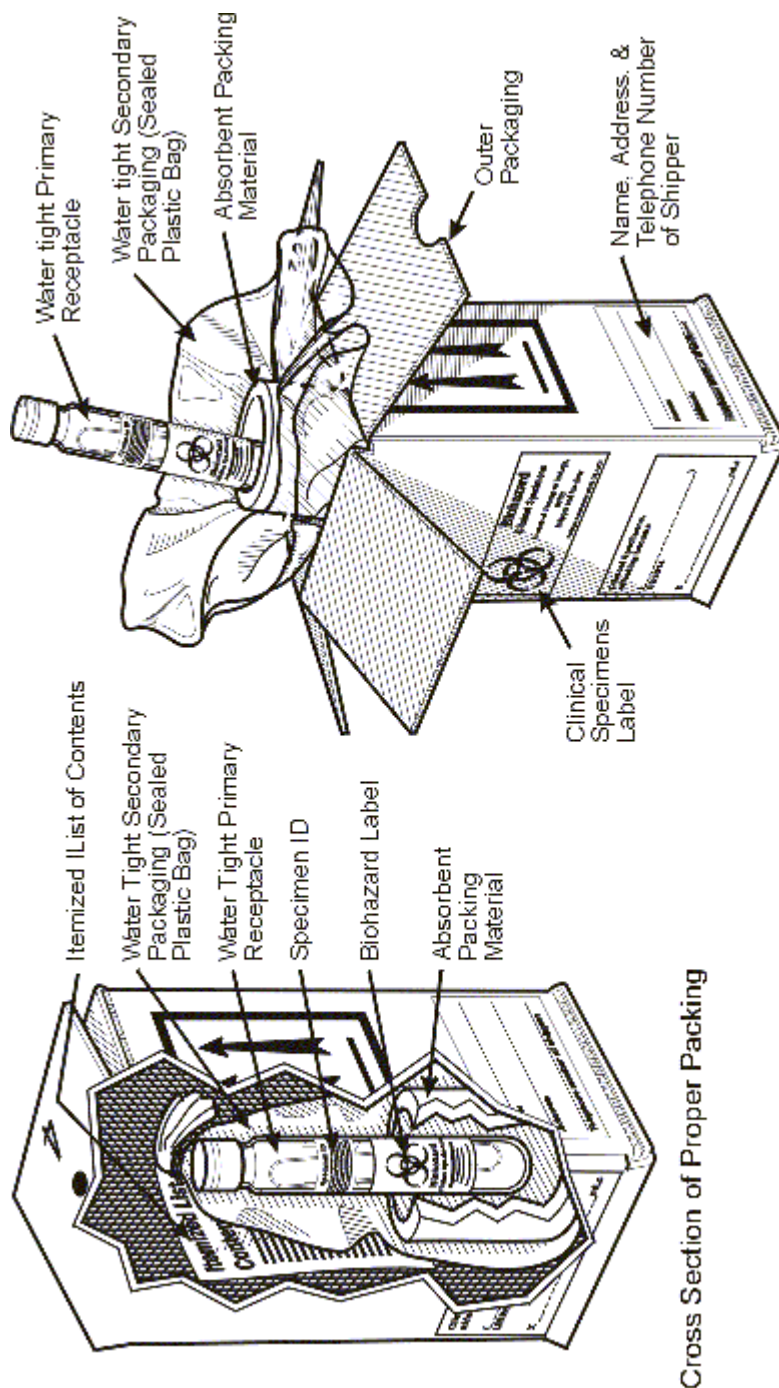
## **DIAGRAMS OF PACKINGS FOR SHIPMENT:**

**Clinical Diagnostic Specimen, (Triple Packaging System)**

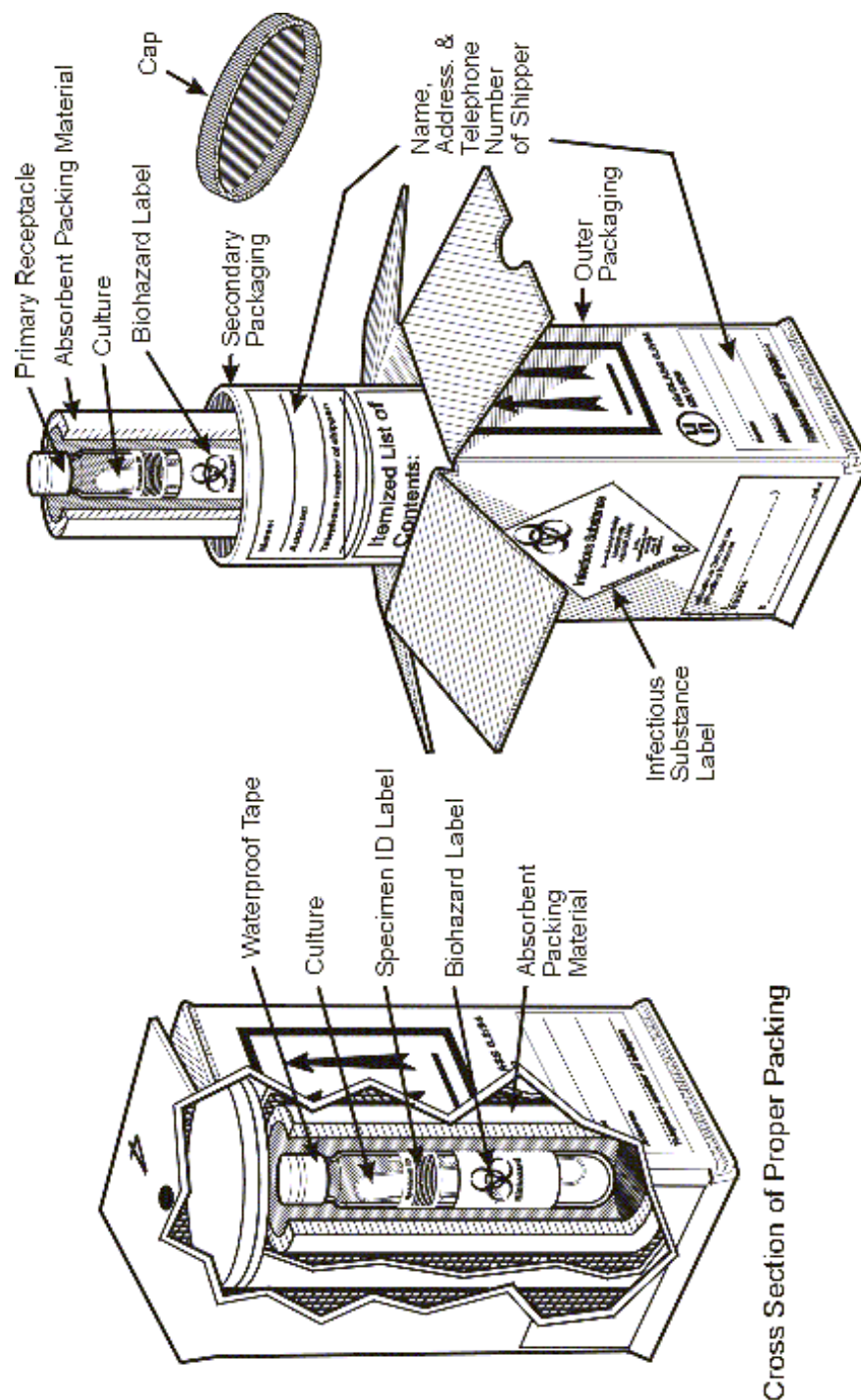
**Infectious Substance, (Triple Packaging System, UN Specified Packagings)**

**Single Overpack, (Dry Ice)**

**Multiple Overpack Shipper for Infectious Substances**

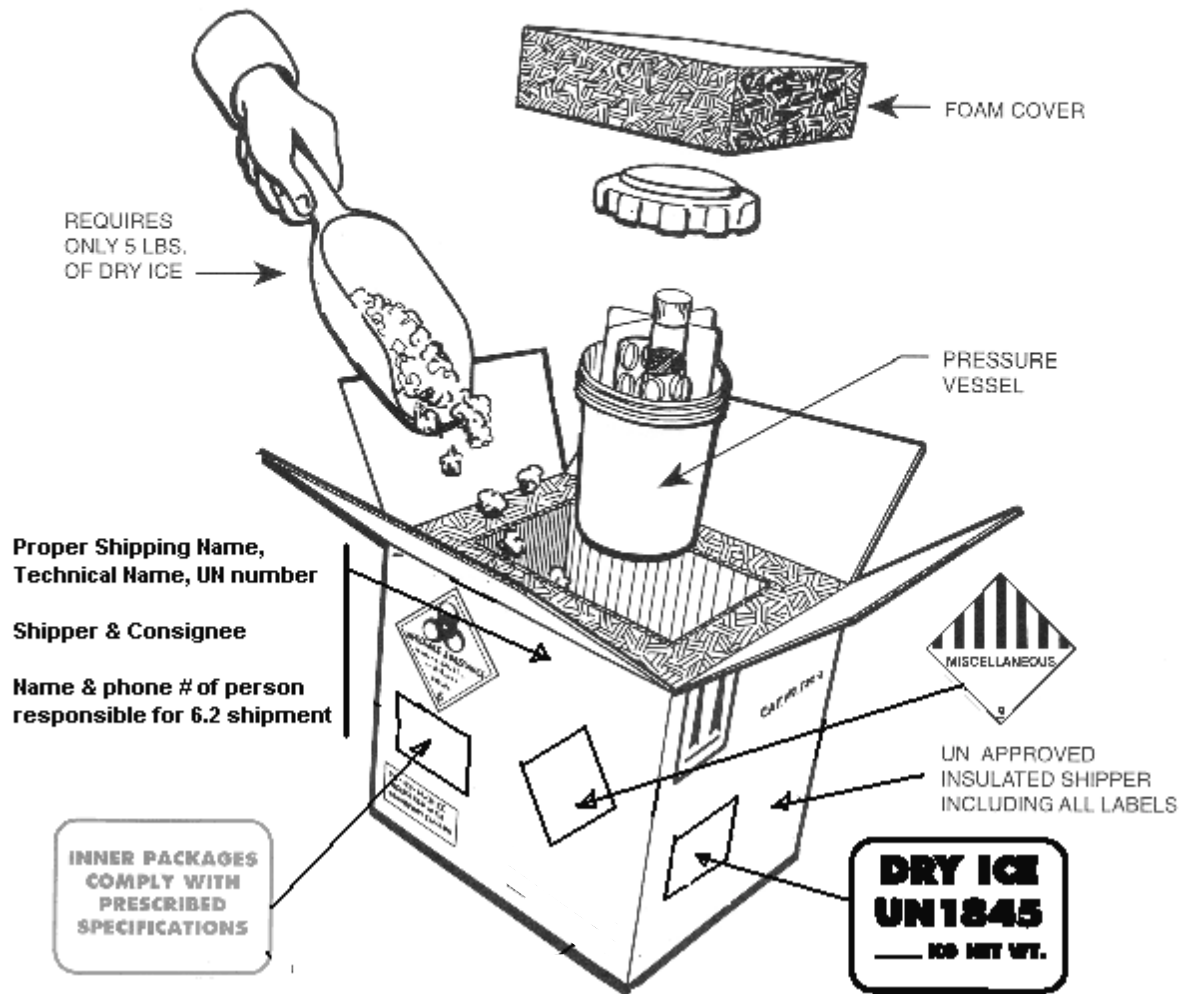


## Packing and Labeling of Clinical Specimens



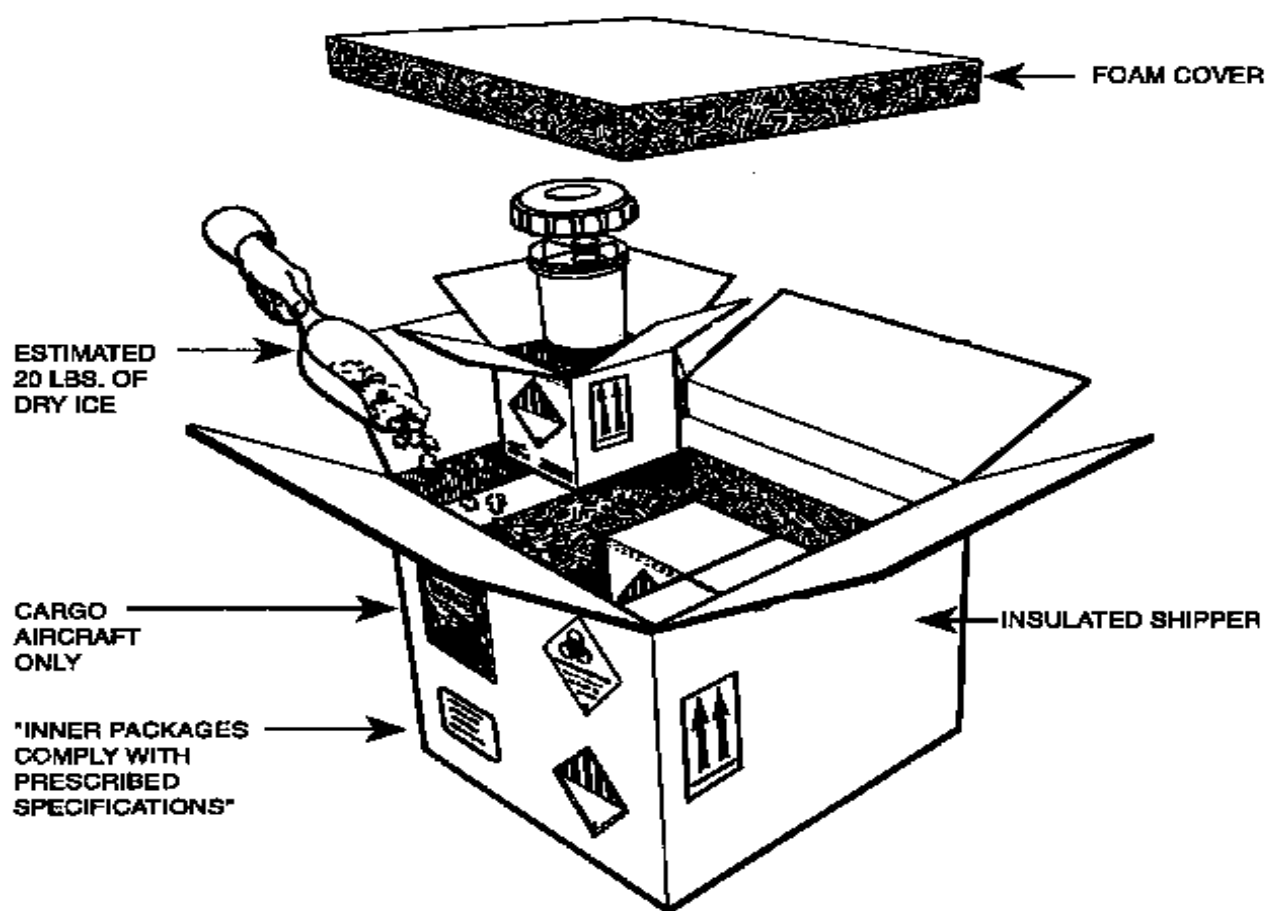
## Packing and Labeling of Infectious Substances

## Infectious Substance, Dry Ice Overpack for frozen or refrigerated specimens



# Infectious Substance Overpack-Shipper

**for frozen or refrigerated specimens**



**REGULATORY AGENCIES AND SOME CARRIERS OF DIAGNOSTIC SPECIMENS AND INFECTIOUS SUBSTANCES**

AGENCY	REGULATIONS	INFECTIOUS SUBSTANCES	DIAGNOSTIC SPECIMENS
<b>WORLD HEALTH ORGANIZATION (WHO)</b> <a href="http://www.who.org">http://www.who.org</a>	GUIDELINES FOR THE SAFE TRANSPORT OF INFECTIOUS SUBSTANCES AND DIAGNOSTIC SPECIMENS GENEVA, 1997 <a href="http://www.who.int/emc/biosafety">http://www.who.int/emc/biosafety</a> <a href="http://www.absa.org/resources/Guides.htm">http://www.absa.org/resources/Guides.htm</a>	MUST MEET IATA PACKAGING REGULATIONS; INSTRUCTION 602; TRIPLE PKG. SYS.	MUST MEET IATA PACKAGING REGULATIONS; INSTRUCTION 650; TRIPLE PKG. SYS.
<b>INTERNATIONAL CIVIL AVIATION ORGANIZATION (ICAO)</b> <a href="http://www.iaco.int">http://www.iaco.int</a>	TECHNICAL INSTRUCTIONS FOR THE SAFE TRANSPORT OF DANGEROUS GOODS BY AIR; (DOC 9284-AN/905): 1997-1998 <a href="http://www.icao.int/icao/en/cat.htm">www.icao.int/icao/en/cat.htm</a>	MUST MEET UN AND IATA PACKAGING REGULATIONS; INSTRUCTION 602 TRIPLE PKG. SYS.	MUST MEET UN AND IATA PACKAGING REGULATIONS; INSTRUCTION 650 TRIPLE PKG. SYS.
<b>INTERNATIONAL AIR TRANSPORT ASSOCIATION (IATA)</b> <a href="http://www.iata.org">www.iata.org</a>	DANGEROUS GOODS REGULATIONS, 41 <sup>ST</sup> EDITION, 01/01/2000 <a href="http://www.dgitraining.com">http://www.dgitraining.com</a>	MUST MEET UN AND IATA PACKAGING REGULATIONS; INSTRUCTION 602 TRIPLE PKG. SYS.	MUST MEET UN AND IATA PACKAGING REGULATIONS; INSTRUCTION 650 TRIPLE PKG. SYS.
<b>UNITED STATES DEPARTMENT OF TRANSPORTATION (USDOT)</b> <a href="http://www.dot.gov">http://www.dot.gov</a>	CLASSIFICATION OF HAZARDOUS MATERIALS FOR TRANSPORTATION, TITLE 49 CODE OF FEDERAL REGULATIONS (PART 171-180) (49CFR Part 171-180), In Revision <a href="http://hazmat.dot.gov/rules/98_3971.htm">http://hazmat.dot.gov/rules/98_3971.htm</a>	DOT REGULATION 49 CFR 173.196. ALSO USE CDC GUIDELINES USPHS 42 CFR PART 72	HAVE NO GUIDELINES OR REGULATIONS IN PLACE. NEW PROPOSED REGULATIONS DRAFTED 09/02/1998
<b>UNITED STATES PUBLIC HEALTH SERVICE CENTER FOR DISEASE CONTROL AND PREVENTION (USPHS-CDC)</b> <a href="http://www.cdc.gov">http://www.cdc.gov</a>	PACKAGING AND HANDLING OF INFECTIOUS SUBSTANCES AND SELECT AGENTS, TITLE 42 CODE OF FEDERAL REGULATIONS, PART 72; (42 CFR Part 72) In Revision <a href="http://www.access.gpo.gov/nara/cfr/cfr-table-search.html">www.access.gpo.gov/nara/cfr/cfr-table-search.html</a>	DOT 49 CFR 173.196. REVISING CURRENT REGULATIONS FOR PACKAGING AND SHIPPING.	MINIMUM REQUIREMENTS. NEW PROPOSED REGULATIONS DRAFTED 10/28/1999.



AGENCY	REGULATIONS	INFECTIOUS SUBSTANCES	DIAGNOSTIC SPECIMENS
<b>UNITED STATES POSTAL SERVICE (USPS)</b> <a href="http://www.usps.gov">http://www.usps.gov</a>	REGULATED BY TITLE 39 CODE OF FEDERAL REGULATIONS, PART 111 (39 CFR Part 111). <a href="http://www.access.gpo.gov/nara/cfr/cfr-table-search.html">www.access.gpo.gov/nara/cfr/cfr-table-search.html</a> SUBJECT TO RESTRICTIONS IN TITLE 18 UNITED STATES CODE 1716 (18 U.S.C. 1716). DOMESTIC MAIL MANUAL (DMM CO23). HAZARDOUS, RESTRICTED, AND PERISHABLE MAIL, PUBLICATION 52, JULY 1999.	USPS 39 CFR (Part 111) USPHS 42 CFR 72.3 DOMESTIC MAIL MANUAL (DMM CO23). PUBLICATION 52, SECTION 346.212 TO 346.5, 1999	SUBJECT TO THE REQUIREMENTS OF THE DOMESTIC MAIL MANUAL CO23.8.4 MAILABLE ITEMS MUST BE SENT AS EXPRESS, PRIORITY OR FIRST-CLASS MAIL.
<b>FEDERAL EXPRESS (FedEx)</b> <a href="http://www.fedex.com">http://www.fedex.com</a>	FOLLOW IATA AND DOT REGULATIONS SEE SPECIFIC CARRIER INSTRUCTIONS <a href="http://www.fedex.com/us/services/">http://www.fedex.com/us/services/</a>	CHECK CDC LISTING FOR SELECT AGENTS <u>ACCEPTABLE IF RISK GROUP 2 OR 3 AND PACKED ACCORDING TO IATA P.I. 602 FOR INFECTIOUS SUBSTANCES.</u>	ACCEPTABLE IF PACKAGED ACCORDING TO IATA REGULATIONS. IATA PACKING INSTRUCTION 650. PACKAGE MUST CONTAIN BIOHAZARD LABEL.
<b>UNITED PARCEL SERVICE (UPS)</b> <a href="http://www.ups.com">http://www.ups.com</a>	FOLLOW DOT REGULATIONS DO NOT SHIP INTERNATIONALLY SEE SPECIFIC CARRIER INSTRUCTIONS	NON-ACCEPTABLE	MUST PACKAGE ACCORDING TO DOT REGULATIONS FOR INFECTIOUS SUBSTANCES. BIOHAZARD LABEL MUST BE ON PKG.
<b>LOCAL COURIER SERVICES</b>	MUST FOLLOW DOT REGULATIONS		
<b>CAB COMPANIES</b>	MUST FOLLOW DOT REGULATIONS		

## INTERNATIONAL AND NATIONAL WEBSITES:

AGENCY:	WEBSITE:	TELEPHONE:	FAX:
International Air Transport Association	<a href="http://www.iata.org">www.iata.org</a> <a href="http://www.iata.org/cargo/dg">www.iata.org/cargo/dg</a>	514-390-6726 514-390-6770	514-874-9659
International Civil Aviation Organization	<a href="http://www.icao.org">www.icao.org</a>	514- 954-8022	514-954-6769
United States Department of Transportation	<a href="http://www.dot.gov">http://www.dot.gov</a>	405-949-0036 ext. 374	405-946-4345
United States Department of Commerce Bureau of Export Administration	<a href="http://www.bra.fedworld.gov">www.bra.fedworld.gov</a> <a href="http://www.bxa.doc.gov">www.bxa.doc.gov</a> <a href="http://www.access.gpo.gov">www.access.gpo.gov</a>	202-482-4811 202-482-5808 949-660-0144	202-482-3617
United States Public Health Service	<a href="http://www.usphs.gov">www.usphs.gov</a>		
The Centers For Disease Control	<a href="http://www.cdc.gov">www.cdc.gov</a>	404-639-3235 404-639-3354	404-639-2294
Laboratory Registration Select Agent Transfer Program/CDC	<a href="http://www.cdc.gov/od/ohs/irsat.htm">www.cdc.gov/od/ohs/irsat.htm</a>	404-639-4418 404-639-4419	404-639-0880
United States Department of Agriculture	<a href="http://www.aphis.usda.gov/oa/">http://www.aphis.usda.gov/oa/</a> click on: imexdir.html		
Dangerous Goods International Training Center; Offer Training in IATA Regulations	<a href="http://www.dgitraining.com">www.dgitraining.com</a>	800-338-2291 650-306-8450	650-306-8459
Federal Aviation Administration	<a href="http://www.faa.gov">www.faa.gov</a>		
Federal Aviation Administration New England Regional Office	<a href="http://www.ane.faa.gov">www.ane.faa.gov</a>	781-238-7705 MA 860-623-5572 CT	781-238-7716 860-292-1360
Hazardous Materials Regulations (RSPA Ctr.) (Headquarters RSPA Center)	<a href="http://www.rspa.dot.gov">www.rspa.dot.gov</a>	800-476-4922	202-366-3012
Hazardous Materials Safety	<a href="http://hazmat.dot.gov">http://hazmat.dot.gov</a>	202-366-4700 609-989-2256	202-366-2784 609-989-2277
Hazardous Materials Advisory Council, Washington, DC	<a href="http://www.hmac.org">www.hmac.org</a>	800-634-1598 202-289-4550	202-289-4074
United States Postal Service	<a href="http://www.usps.gov">www.usps.gov</a>	call your local P.O.	
Federal Express FedEx Dangerous Goods Hotline	<a href="http://www.fedex.com">www.fedex.com</a>	800-463-3339 800-633-7019	
United Parcel Service, Hazardous Materials Support Center	<a href="http://www.ups.com">www.ups.com</a>	800-554-9964	

<b>AGENCY:</b>	<b>WEBSITE:</b>	<b>TELEPHONE:</b>	<b>FAX:</b>
Saf-T-Pak Offers course in shipping diagnostic Specimens and infectious substances According to IATA Regulations.	<a href="http://www.saftpak.com">www.saftpak.com</a>	800-814-7484 780-486-0211	780-486-0235 888-814-7484
Transportation Safety Institute (TSI) Offers course in DOT Regulations The course covers infectious substances, Biological products, diagnostic specimens And genetically modified organisms.	<a href="http://www.tsi.dot.gov">Http://www.tsi.dot.gov</a> <a href="http://www.text-trieve.com/tsi">Www.text-trieve.com/tsi</a>	405-949-0036 ext 374	405-946-4345
Environmental Resource Center Offers course in DOT Regulations	<a href="http://www.ercweb.com">www.ercweb.com</a>	800-537-2372 919-469-1585	919-469-4137
State Laboratory Institute Massachusetts Department of Public Health	<a href="http://www.state.ma.us/dph/sli.htm">http://www.state.ma.us/dph/sli.htm</a>	617-983-6656	617-983-6210
United Nations Sub-Committee of Experts	<a href="http://www.unece.org/trans">http://www.unece.org/trans</a> (Click on reports)		
Transport Canada	<a href="http://www.tc.gc.ca">www.tc.gc.ca</a> <a href="http://www.tc.gc.ca/acts/regs">Www.tc.gc.ca/acts/regs</a>		
For information on classification of organisms according to risk:	<a href="http://www.absa.org/riskgroups/index.htm">www.absa.org/riskgroups/index.htm</a> Or <a href="http://www.hc-sc.gc.ca/hpd/lcdc/biosafety/docs/index.html">www.hc- sc.gc.ca/hpd/lcdc/biosafety/docs/in dex .html</a>		

**SOME SUPPLIERS AND/OR MANUFACTURERS OF UN CERTIFIED PRODUCTS USED FOR  
SHIPPING DIAGNOSTIC SPECIMENS AND INFECTIOUS SUBSTANCES:**

Action Pak, Inc.  
2550 Pearl Buck Road  
Bristol, PA 19007  
Phone: 800-755-9764  
Fax: 215-788-1760  
Web: <http://www.actionpakinc.com>

Casing Corporation  
P.O. Box 820369  
Dallas, TX 75382  
Phone: 800-358-6866  
Fax: 214-392-4418  
Web: <http://www.casingcorp.com>

Air Sea Atlanta, Inc.  
1234 Logan Circle  
Atlanta, GA 30318  
Phone: 404-351-8600  
Fax: 404-351-4005  
Web: <http://www.airseaatlanta.com>

Cin-Made Packaging Group, Inc.  
1780 Dremnan Avenue  
Cincinnati, Ohio 45223  
Phone: 513-681-3600  
Fax: 513-541-5945  
E-mail: [maryalice@cin-made.com](mailto:maryalice@cin-made.com)  
Web: [www.cin-made.com](http://www.cin-made.com)

Air Sea Containers, Inc.  
2749 NW 82nd Avenue  
Miami, FL 33122  
Phone: 888-272-9883  
Fax: 305-599-1668  
E-mail: [sales@airseacontainers.com](mailto:sales@airseacontainers.com)  
Web: <http://www.airseacontainers.com>

The Compliance Center, Inc.  
2150 Liberty Drive  
Niagara Falls, NY 14304  
Phone: 800-767-7231  
Fax: 716-283-2764  
Web: [www.thecompliancecenter.com](http://www.thecompliancecenter.com)

All-Pak, Inc.  
Corporate One West  
1195 Washington Pike  
Bridgeville, PA. 15017  
Phone: 800-245-2283  
Fax: 412-257-3001  
Web: <http://www.allpakinc.com>

Dangerous Goods.Com  
P O Box 60543  
Houston, TX 77205  
Phone: 281-821-0859  
Fax: 281-821-6558  
E-mail: [larry@dangerousgoods.com](mailto:larry@dangerousgoods.com)  
Web: [www.dangerousgoods.com](http://www.dangerousgoods.com)

Allflex Hazardous Material Packaging, Inc.  
105 Race Street  
Amber, PA 19002  
Phone: 800-448-2467  
Fax: 215-643-3339  
E-mail: [sales@allflex.com](mailto:sales@allflex.com)  
Web: [www.allflex.com](http://www.allflex.com)

Dangerous Goods Management  
14335-C Interdrive West  
Houston, TX 77032  
Phone: 281-442-8434  
Fax: 281-442-6055  
E-mail: [jean@dgm-usa.com](mailto:jean@dgm-usa.com)  
Web: [www.dgmsupport.com](http://www.dgmsupport.com)

Cargo Pak Corporation  
3215 Wellington Court  
Raleigh, NC  
Phone: 800-266-0652  
Fax: 919-878-9244  
E-mail: [rsmith@cargopac.com](mailto:rsmith@cargopac.com)  
Web: <http://www.cargopak.com>

DG Supplies, Inc.  
28 C Industrial Drive  
Hamilton, NJ 08619  
Phone: 800-347-7879  
Fax: 609-584-5744  
E-mail: [sales@dgsupplies.com](mailto:sales@dgsupplies.com)  
Web: <http://www.dgsupplies.com>

Environmental Packaging Sys. Ltd.  
1 Research Drive  
Dartmouth, NS, Canada B2Y 4M9  
Phone: 800-277-8675  
Fax: 902-466-6889  
E-mail: [akachar@ep-systems.ns.ca](mailto:akachar@ep-systems.ns.ca)  
Website: none

EXAKT Technologies, Inc.  
7416 North Broadway Extension, Suite E  
Oklahoma City, OK 73116  
Phone: 800-866-7172  
Fax: 405-848-7701  
E-mail: [infopak@exaktusa.com](mailto:infopak@exaktusa.com)  
Web: [www.exaktpak.com](http://www.exaktpak.com)

Federal Industries Corp.  
2550 Niagara Lane  
Plymouth, MN 55447  
Phone: 800-523-9033  
Fax: 612-476-8155  
E-mail: [chem-tran@aol.com](mailto:chem-tran@aol.com)  
Web: [www.chemtran.com](http://www.chemtran.com)

Freund Can Company  
155 West 84th St.  
Chicago, IL 60620  
Phone: 773-224-4230  
Fax: 773-224-8812  
E-mail: [customerservice@freundcan.com](mailto:customerservice@freundcan.com)  
Web: <http://www.freundcan.com>

General Container Corporation  
P O Box 6140  
Somerset, NJ 08875  
Phone: 732-435-0020  
Fax: 732-435-0040  
E-mail: [gencon@eclipse.net](mailto:gencon@eclipse.net)  
Web: <http://www.generalcontainer.com>

Hazmatpac, Inc.  
5301 Polk Avenue, Bldg. 18  
Houston, TX 77023  
Phone: 800-923-9123  
Fax: 713-923-1111  
E-mail: [hazmatpac@hazmatpac.com](mailto:hazmatpac@hazmatpac.com)  
Web: <http://www.hazmatpac.com>

Industrial Crating & Packing, Inc.  
P O Box 88299  
Seattle, WA 98138  
Phone: 425-226-9200  
Fax: 425-226-9205  
E-mail: [indcrate@earthlink.net](mailto:indcrate@earthlink.net)  
Web: <http://www.indcrate.com>

Inmark, Inc.  
P.O. Box 43309  
220 Fisk Drive, SW  
Atlanta, GA 30336  
Phone: 404-267-2020  
Fax: 404-267-2021  
E-mail: [sales@inmarkinc.com](mailto:sales@inmarkinc.com)  
Web: <http://www.inmarkinc.com>

LabelMaster  
5724 North Pulaski Road  
Chicago, IL 60646  
Phone: 800-621-5808  
Fax: 800-723-4327  
E-mail: [sales@labelmaster.com](mailto:sales@labelmaster.com)  
Web: [www.labelmaster.com](http://www.labelmaster.com)

LPS Industries  
10 Caesar Place  
Moonachie, NJ 07074  
Phone: 800-242-7628  
Fax: 201-438-1326  
E-mail:  
Web: <http://www.psind.com>

Nefab Inc.  
736 West Estes Ave.  
Schaumburg, IL 60193  
Phone: 847-985-1600  
Fax: 847-985-3200  
E-mail:  
Web: <http://www.nefab.com>

O'Berk International, Inc.  
3 Milltown Court  
P.O. Box 1690  
Union, NJ 07083  
Phone: 800-577-7624  
Fax: 908-687-5157  
E-mail: [obi@oberk.com](mailto:obi@oberk.com)  
Web: <http://www.aluminiumbottles.com>

Polyfoam Packers Corporation  
2320 Foster Avenue  
Wheeling, IL 60090  
Phone: 800-323-7442  
Fax: 847-398-0653  
E-mail: [info@polyfoam.com](mailto:info@polyfoam.com)  
Web: <http://www.polyfoam.com>

Saf-T-Pac, Inc.  
101, 17872-106 Avenue  
Edmonton, Alberta, Canada T5S 1V4  
Phone: 800-841-7484  
Fax: 780-486-0235  
E-mail:  
Web: <http://www.saftpak.com>

ProPack, Inc.  
76 Jansen Avenue  
Essington, PA 19029  
Phone: 610-521-4050  
Fax: 610-521-8737  
E-mail: [dg.propack@erols.com](mailto:dg.propack@erols.com)  
Web: <http://www.propack.com>

Source Packaging of New England, Inc.  
405 F Kilvert Street  
Warwick, RI 02866  
Phone 800-200-0366  
Fax: 401-738-7762  
E-mail: [sales@sourcepak.com](mailto:sales@sourcepak.com)  
Web: <http://www.sourcepak.com>

Russell-Stanley Corp.  
685 Route 202/206  
Bridgewater, NJ 08807  
Phone: 908-203-9500  
Fax: 908-203-1944  
E-mail: [info@russell-stanley.com](mailto:info@russell-stanley.com)  
Web: [www.russell-stanley.com](http://www.russell-stanley.com)

May 01, 2001